IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of Marius Filtvedt et al.	)	Examiner: Huong Q. Pham Art Unit: 3772
Serial No.: 10/749,150	)	Atty. Docket No. 49281.1.2
Filed: December 30, 2003	)	
For: DEVICE FOR APPLYING A PULSATING PRESSURE TO A LOCAL REGION OF THE BODY AND THE APPLICATIONS THEREOF	)	

To: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SECOND REVISED APPEAL BRIEF (37 C.F.R § 41.37)

This is an appeal of the Examiner's final rejection of claims 1-27, 29, 30, 32-43, 47-52, 54-58, 60-67, and 69-82, in the Final Office Action issued on May 7, 2007 and is a revised and replacement Appeal Brief of that originally filed on January 18, 2008. This is responsive to the Notification of Non-Compliant Appeal Brief mailed May 28, 2008.

REAL PARTY IN INTEREST.

The real party in interest is THERMONOR AS, the assignee of record.

RELATED APPEALS AND INTERFERENCES.

None.

STATUS OF CLAIMS.

Claims 1-27, 29, 30, 32-52, 54-67, and 69-82 are pending in this case. Claims 44-46 and 59 have been withdrawn; claims 28, 31, 53, and 68 have been cancelled; and claims 1-27, 29, 30, 32-43, 47-52 54-58, 60-67 and 69-82 have been finally rejected. Applicants are appealing the Examiner's final rejection of claims 1-27, 29, 30, 32-43, 47-52, 54-58, 60-67, and 69-82. A copy of the appealed claims is provided in the Claims Appendix near the end of this document.

STATUS OF AMENDMENTS.

Applicants have made no amendments to the claims since the May 7, 2007 Final Office Action. In response to the Final Office Action, Applicants filed their Notice of Appeal on August 7, 2007, without further amendment.

SUMMARY OF CLAIMED SUBJECT MATTER.

The subject matter defined in independent claim 1 finds support in both the specification and the drawings. The device for applying a pulsating pressure to a local region of the body finds support, for example, at page 30, lines 1-11 and in Figure 1 as reference number 3. The pressure chamber in to which a limb of the body can be placed to seal it from external conditions finds support, for example, at page 30, lines 2-4 and in Figure 1 as reference number 4. Immersing a limb in a liquid contained in the pressure chamber such that the liquid surrounds and is in contact with the limb finds support, for example, at page 30, lines 8-9 and generally in Figure 1. An element for generating pulses of negative pressure within the chamber that can be transmitted to the

limb directly via the liquid finds support, for example, at page 7, lines 7-9 and generally in Figure 1. The element being adapted to generate negative pressure for between 1 and 20 seconds and to release negative pressure for between 2 and 15 seconds finds support, for example, at page 10, lines 1-12.

The subject matter defined in independent claim 25 finds support in both the specification and the drawings. The method of applying a pulsating pressure to a local region of the body finds support, for example, at page 6, lines 13-20 and generally in Figure 1. Providing a pressure chamber finds support, for example, at page 6, lines 13-20 and generally in Figure 1. Introducing a limb in to the pressure chamber such that it is sealed from external conditions finds support, for example, at page 6, lines 13-20 and generally in Figure 1. Filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid finds support, for example, at page 6, lines 13-20 and generally in Figure 1. Generating a pulsating negative pressure within the chamber and transmitting the pulses of negative pressure to the limb directly via the liquid finds support, for example, at page 6, lines 13-20 and generally in Figure 1. Each pulse of negative pressure being generated for between 1 and 20 seconds and released for between 2 and 15 seconds finds support, for example, at page 10, lines 1-12.

The subject matter defined in independent claim 47 finds support in both the specification and the drawings. The device for applying a pulsating pressure to an area of skin on a limb of a body finds support, for example, at page 27, line 22 through page 28 line 5 in Figure 9 as reference number 3. The pressure chamber into which the limb can be inserted finds support, for example, at page 34, lines 6-16 and in Figure 9 as

reference number 4. The barrier layer of flexible material housed within that chamber for form-fitted engagement against the skin finds support, for example, at page 34, lines 6-16 and in Figure 9 as reference number 37. The barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from an outer region having a flow of liquid within the chamber finds support, for example, at page 34, lines 6-16 and generally in Figure 9. The device including an element or means for generating a pulsating negative pressure within the pressure chamber finds support, for example, at page 34, lines 6-16 and generally in Figure 9. The device including an element or means for generating a negative pressure between the barrier layer and the area of skin to maintain the barrier layer in contact with the area of skin finds support, for example, at page 34, lines 6-16 and generally in Figure 9. The element or means for generating negative pressure being in communication with the inner region but not with the outer region finds support, for example, at page 34, lines 6-16 and generally in Figure 9.

The subject matter defined in independent claim 48 finds support in both the specification and the drawings. The method of treating hypothermia in a human body by applying a pulsating pressure to a local region of that body finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Providing a pressure chamber finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Introducing a limb in to the pressure chamber such that it is sealed from external conditions finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by

and in contact with the liquid finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Circulating the liquid via a heat exchanger unit to heat the liquid to a temperature of 40°C or above finds support, for example, at page 24, lines 21-22. Generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa) finds support, for example, at page 20, lines 3-10. Each pulse of negative pressure being generated for between 1 and 20 seconds and released for an interval of between 2 and 15 seconds finds support, for example, at page 13, line 20 through page 14, line 7. The pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid finds support, for example, at page 11, lines 1-5.

The subject matter defined in independent claim 50 finds support in both the specification and the drawings. The method of treating hyperthermia in a human body by applying a pulsating pressure to a local region of that body finds support, for example, at page 38, line 17. Providing a pressure chamber finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Introducing a limb into the pressure chamber such that it is sealed from external conditions finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Circulating the liquid via a heat exchanger unit to cool the liquid to a temperature of 30°C or less finds support, for example, at page 24, lines 23-24. Generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa

and -10.7 kPa) finds support, for example, at page 20, lines 3-10. Each pulse of negative pressure being generated for between 1 and 20 seconds and released for an interval of between 2 and 15 seconds finds support, for example, at page 13, line 20 through page 14, line 7. The pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid finds support, for example, at page 11, lines 1-5.

The subject matter defined in independent claim 52 finds support in both the specification and the drawings. The method of increasing blood flow to a local region of the body finds support, for example, at page 6, lines 13-21 and generally in Figure 1. Providing a pressure chamber finds support, for example, at page 6, lines 13-21 and generally in Figure 1. Introducing the local region of the body into the pressure chamber such that the local region is sealed from external conditions finds support, for example, at page 6, lines 13-21 and generally in Figure 1. Introducing liquid into the pressure chamber so that the local region of the body is substantially surrounded by and in direct contact with the liquid finds support, for example, at page 6, lines 13-21 and generally in Figure 1. Alternately generating negative pressure for a predetermined time interval of 1 to 20 seconds and releasing negative pressure for a predetermined time interval of 2 to 15 seconds within the chamber finds support, for example, at page 12, lines 1-10. The negative pressure being transmitted to the local region through direct contact with the liquid finds support, for example, at page 6, lines 7-12.

The subject matter defined in independent claim 61 finds support in both the specification and the drawings. The method of applying a pulsating negative pressure to a local region of the body finds support, for example, at page 12, line 24 through page 13,

line 8 and generally in Figure 1. Providing a pressure chamber containing a gas finds support, for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1. Introducing a limb into the pressure chamber such that the limb is sealed from external conditions finds support, for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1. Partially filling the pressure chamber with a liquid so that the limb is substantially surrounded by and in direct contact with the liquid while leaving a gas pocket above the liquid in an upper region of the chamber finds support, for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1. Continuously supplying a constant negative pressure into the gas pocket finds support, for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1. Introducing a positive pressure into the gas pocket for between 2 and 15 seconds to temporarily release negative pressure within the chamber and to temporarily produce a net positive pressure in the gas pocket finds support, for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1 and at page 12, lines 3-7.

The subject matter defined in independent claim 62 finds support in both the specification and the drawings. The method of transferring thermal energy to and from a body finds support, for example, at page 13, lines 9-20 and generally in Figure 1. Providing an enclosure finds support, for example, at page 13, lines 9-20 and generally in Figure 1. Introducing a limb into the enclosure such that the limb is sealed from external conditions finds support, for example, at page 13, lines 9-20 and generally in Figure 1. Introducing thermal exchange liquid into the chamber so that the limb is completely surrounded by and in direct contact with the liquid finds support, for example, at page 13, lines 9-20 and generally in Figure 1. The introduced thermal

exchange liquid having a predetermined temperature different than the core body temperature finds support, for example, at page 13, lines 9-20. Circulating the introduced thermal exchange liquid around the surfaces of the limb, the liquid transmitting heat to or from the limb finds support, for example, at page 13, lines 9-20 and generally in Figure 1. Generating a pulsating negative pressure within the enclosure finds support, for example, at page 13, lines 9-20 and generally in Figure 1. The pulsating negative pressure being transmitted to the limb through direct contact with the thermal exchange liquid finds support, for example, at page 13, lines 9-20 and generally in Figure 1. Generating pulsating negative pressure including alternately generating negative pressure for between 1 and 20 seconds and releasing negative pressure for between 2 and 15 seconds finds support, for example, at page 12, lines 1-10.

GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL.

Claims 1, 25, 29-30, 32-33, 52, 54, 62, 64-65, and 69-76 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 3,292,613 to MacLeod ("MacLeod").

Claims 9-10 and 38 stand rejected under 35 U.S.C. § 103(a) as obvious over MacLeod in view of U.S. Patent No. 3,094,983.

Claims 17-18, 26-27, 35, 48-51, 55-56, 66-67, and 79-82 stand rejected under 35 U.S.C. § 103(a) as obvious over MacLeod in view of U.S. Patent No. 5,683,438 to Grahn ("Grahn") and U.S. Patent No. 3,878,839 to Norton et al. ("Norton").

Claims 19-24 and 43 stand rejected under 35 U.S.C. § 103(a) as obvious over MacLeod in view of Grahn and Norton and further in view of U.S. Patent No. 3,896,794 to McGarath and U.S. Patent No. 4,186,732 to Christoffel.

Claims 39-42 stand rejected under 35 U.S.C. § 103 as obvious over MacLeod in view of U.S. Patent No. 3,094,983 and further in view of Grahn.

Claims 47 and 61 stand rejected under 35 U.S.C. § 102(b) as anticipated by Norton.

Copies of each of the above-identified references are attached in the Evidence Appendix near the end of this document.

ARGUMENT.

A. The Board Should Reverse the Final Office Action's Rejection of Claims 1, 25, 29-30, 32-33, 52, 54, 62, 64-65, and 69-76 Because MacLeod Does Not Anticipate Them Under 35 U.S.C. § 102(b) or Render Them Obvious Under 35 U.S.C. § 103(a).

1. MacLeod Does not Disclose the Negative Pressure Pulses of Specific Duration Recited in Independent Claims 1, 25, 52, and 62.

Applicants respectfully submit that the Final Office Action errs in asserting that MacLeod discloses negative pressure pulses of specific duration as recited in independent claims 1, 25, 52, and 62. The relevant limitations in those claims are as follows:

- claim 1 – "wherein an element is provided to generate pulses of negative pressure within the chamber that can be transmitted to the limb directly via the liquid, the element being adapted to generate negative pressure for *between 1 and 20 seconds* and to release negative pressure for *between 2 and 15 seconds*"
- claim 25 – "generating a pulsating negative pressure within the chamber and transmitting the pulses of negative pressure to the limb directly via the liquid, wherein each pulse of negative

pressure is generated for *between 1 and 20 seconds* and released for *between 2 and 15 seconds*"

- claim 52 – "alternately generating negative pressure for a predetermined time interval of *1 to 20 seconds* and releasing negative pressure for a predetermined time interval of *2 to 15 seconds* within the chamber, the negative pressure being transmitted to the local region through direct contact with the liquid"
- claim 62 – "generating a pulsating negative pressure within the enclosure, the pulsating negative pressure being transmitted to the limb through direct contact with the thermal exchange liquid, wherein generating pulsating negative pressure includes alternately generating negative pressure for *between 1 and 20 seconds* and releasing negative pressure for *between 2 and 15 seconds*"

As can be seen, each claim recites pressure generation for between 1 and 20 seconds and pressure release for between 2 and 15 seconds. Thus, the shortest claimed negative pressure pulse is 3 seconds (1 second generation and 2 seconds release).

The Final Office Action rejects all of these independent claims based on MacLeod. With respect to the claimed pressure pulse durations, the Final Office Action states only,

> "MacLeod (3,292,613) teaches that ' the pressure can be synchronized to the heart beat or can be applied less or more frequenly [sic] and in regular multiples of a heart beat , for example, during every second or third heart beat....., or the pressure can be applied irregularly with respect to the heartbeat.' (column 5, lines 9-20). Therefore, the device of Macleod is capable of providing the recited pressures . Note that the rate of the heartbeat is different from one person to another. While the rate of the heartbeat of one person might be about every second or more, note that the rate of the heartbeat of another person (for example, a person who is sleeping , or in a state of relaxation, or in a meditation state , etc.) might be much longer than one second."

(Final Office Action at 4.) Applicants agree that MacLeod teaches synchronizing pressure pulses with a patient's heartbeat. However, parting ways with the Final Office

Action, Applicants conclude that MacLeod's pressure pulses are significantly shorter than those of independent claims 1, 25, 52, and 62.

For a device that synchronizes pressure pulses with a patient's heartbeat to produce a 3-second pressure pulse, the patient's heart rate would have to be 20 beats per minute. Such a heart rate is pathological and would require urgent care or risk death. Even an Olympic athlete has a heart rate around 40 beats per minute when sleeping, which is double what would be required for the MacLeod device to produce a 3-second pressure pulse. Accordingly, Applicants submit that it is unreasonable to read MacLeod as referring to a patient with a heart rate of 20 beats per minute. Rather, a reasonable reading of MacLeod assumes a heart rate of a normal person—along the lines of 60 beats per minute. Based on this reading, MacLeod teaches pressure pulses that last roughly one second, which is significantly shorter than each of the claimed ranges. Accordingly, Applicants respectfully submit that the Final Office Action's rejection of independent claims 1, 25, 52, and 62 based on MacLeod is improper.

Moreover, the specification of the present application describes several advantages over systems like that of MacLeod, which produce pressure pulses synchronized to a patient's heartbeat. For example, page 21 (lines 15-17)states,

> "In a number of earlier known systems in which an oscillating pressure was applied to a patient, it was thought best to vary pressure in time with the heart beat. The present inventors have found that a longer period to the oscillation is better."

Additionally, the following portions of the specification describe how longer pressure pulses produce remarkable increases in blood velocity without constricting the diameter of the blood vessels:

- "[I]t has been found that a preferred embodiment can improve

blood velocity by up to at least 30% in the brachial artery." (Page 15, lines 9-10.)

- "In experiments, an average of at least 50% increase in blood velocity and an increase of 200% in a single subject have been witnessed. By pulsating the pressure, it is believed to facilitate the immediate and repeated increase of blood velocity without inducing a reflex constriction as a result of the venus pooling." (Page 15, lines 10-14.)
- "Figure 4 shows a detailed one minute recording. The negative pressure is built up for 10 seconds and released for 7 seconds (upper panel). The blood velocity in the brachial artery is measured outside the pressure chamber 4. The blood velocity increases to a certain point, about -25 mmHg (-3.4 kPa), before it drops. This is thought to be due to a reflex constriction of the arteries because of the venus pooling. Letting the pressure drop again, facilitates the immediate and repeated increase of blood velocity without the reflex restricting the blood flow as can happen with a constant negative pressure." (Page 31, line 21 through page 32, line 2.)

The test trial discussed on pages 36-38 of the specification cites even more advantages provided by embodiments of the present invention. Accordingly, because Applicants submit that the present invention is patentable over MacLeod, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of claims 1, 25, 52, and 62, along with all claims depending therefrom.

2. *MacLeod Does not Disclose the Negative Pressure Pulses of Even More Specific Duration Recited in Dependent Claims 29-30, 32-33, 54, 64-65, and 69-76.*

Applicants likewise submit that the Final Office Action errs in asserting that negative pressure pulses of more specific duration as recited in dependent claims 29-30, 32-33, 54, 64-65, and 69-76 would have been obvious in light of MacLeod. The durations recited in these claims are as follows:

- Depending from claim 1:

- ⇨ claim 69 – "wherein the element is adapted to release negative pressure for between 5 and 10 seconds"
- ⇨ claim 70 – "wherein the element is adapted to release negative pressure for 7 seconds"
- ⇨ claim 71 – "wherein the element is adapted to generate negative pressure for between 5 and 15 seconds"
- ⇨ claim 72 – "wherein the element is adapted to generate negative pressure for 10 seconds"
- ⇨ claim 73 – "wherein the element is adapted to generate negative pressure for between 5 and 15 seconds and to release negative pressure for between 5 and 10 seconds"
- ⇨ claim 74 – "wherein the element is adapted to generate negative pressure for between 5 and 15 seconds and to release negative pressure for 7 seconds"
- ⇨ claim 75 – "wherein the element is adapted to generate negative pressure for 10 seconds and to release negative pressure for between 5 and 10 seconds"
- ⇨ claim 76 – "wherein the element is adapted to generate negative pressure for 10 seconds and to release negative pressure for 7 seconds"

- Depending from claim 25:
  - ⇨ claim 29 – "wherein each pulse of negative pressure is generated for between 5 and 15 seconds"
  - ⇨ claim 30 – "wherein each pulse of negative pressure is generated for 10 seconds"
  - ⇨ claim 32 – "wherein each pulse of negative pressure is generated for between 5 and 15 seconds" and "wherein the negative pressure is released for an interval of between 5 and 10 seconds at a time to create the pulses of negative pressure"
  - ⇨ claim 33 – "wherein each pulse of negative pressure is generated for 10 seconds" and "wherein the negative pressure is released for 7 seconds at a time to create the pulses of negative pressure"

- Depending from claim 52:
  - ⇨ claim 54 – "wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative pressure for a time interval of about 10 seconds and releasing the negative pressure for a time

interval of about 7 seconds"

- Depending from claim 62:
  - ⇨ claim 64 – "wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative pressure for a time interval of between about 5 and 15 seconds and releasing the negative pressure for a time interval of between about 5 and 10 seconds"
  - ⇨ claim 65 – "wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative pressure for a time interval of about 10 seconds and releasing the negative pressure for a time interval of about 7 seconds"

As can be seen, the negative pressure pulses of these claims are all significantly longer than those of the independent claims. The shortest would have pressure generation for 1 second and pressure release for 5 seconds (claim 69), resulting in a 6-second negative pressure pulse. The other claims recite longer negative pressure pulses.

The Final Office Action rejects each of these claims based only on unsupported assertions that the claimed negative pressure pulses would have been obvious. Specifically, pages 5-6 of the Final Office Action state,

> "As for claims 29-30, 32-33, 54, 64 –65, 69- 76, note that the claimed time intervals are results of obvious experiments and observations , which are well within the realm of one ordinary skill in the art, and do not provide any unobvious result, and therefore are not patentable over prior art. Note that MacLeod (3,292,613) teaches that ' the pressure can be synchronized to the heart beat or can be applied less or more frequenly [sic] and in regular multiples of a heart beat , for example, during every second or third heart beat....., or the pressure can be applied irregularly with respect to the heartbeat.' (column 5, lines 9-20). Providing this teaching of MacLeod (3,292,613) wherein the pressure can be applied less frequently in regular multiples of a heartbeat (i.e., in about at least more than one second , or longer), the exact optimum time intervals can be defined by obvious experiments and observations to provide optimum results, which are well within the realm of one ordinary skill in the art, and which do not provide any unexpected results, and therefore is not patentable over prior art."

Applicants respectfully submit that the evidence of record refutes the assertion that the dependent claims' pressure pulses recited above are obvious. The most important piece of evidence is the Rule 1.132 Affidavit of Erling Bekkestad Rein, submitted on February 15, 2007. In his Affidavit, Mr. Rein details an experiment he conducted to test the efficacy of applying the claimed negative pressure pulses. (Affidavit at 3-11.) Applicants encourage the Board to review this detailed explanation. Based on this experiment, Mr. Rein concludes, "The results show that applying pulses of negative pressure at the claimed intervals has a remarkable impact on blood velocity, while doing so at other intervals does not." (*Id.* at 3.)

Applicants also respectfully submit that secondary considerations (see MPEP 2141(III)) likewise support Applicants' position that the dependent claims' pressure pulses are nonobvious. Mr. Rein's Affidavit notes that he and his co-inventor were able to publish an article titled "Hypothermia During Laparotomy Can Be Prevented by Locally Applied Warm Water and Pulsating Negative Pressure" in the prestigious British Journal of Anaesthesia. This shows that those skilled in the art have taken notice of at least certain aspects of the present invention. Moreover, Mr. Rein's Affidavit also notes that sales of a commercial embodiment of the present invention have earned $500,000—a tribute to the present invention's commercial success. Indeed, Applicants submit that neither the peer recognition nor the commercial success would have resulted if the present invention was nothing more than an obvious extension of MacLeod's 45-year-old technology. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of dependent claims 29-30, 32-33, 54, 64-65, and 69-76.

B. The Board Should Reverse the Final Office Action's Rejection of Claims 9-10 and 38 Because They Are Not Rendered Obvious by MacLeod in View of U.S. Patent No. 3,094,983.

Claims 9-10 depend from claim 1, and claim 38 depends from claim 25. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of these claims for the reasons set forth in Section A under the Argument Heading.

C. The Board Should Reverse the Final Office Action's Rejection of Claims 17-18, 26-27, 35, 48-51, 55-56, 66-67, and 79-82 Because They Are Not Rendered Obvious by MacLeod in View of Grahn and Norton.

1. *Claims 17-18, 26-27, 35, 55-56, 66-67, and 79-82 Depend from Allowable Claims, as Established Above.*

Claims 17-18, 79-80 depend from claim 1; claims 26-27 depend from claim 25; claims 55-56 depend from claim 52; and claims 66-67 depend from claim 62. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of these claims for the reasons set forth in Section A under the Argument Heading.

2. *MacLeod Does not Disclose the Negative Pressure Pulses of Specific Duration Recited in Claims 48-51 and 81-82.*

Applicants respectfully submit that the Board should reverse the Final Office Action's rejection of claims 48-51 for the same reasons set forth in the previous section. The relevant limitations of independent claims 48 and 50 are as follows:

- claim 48 – "generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -

10.7 kPa), each pulse of negative pressure being generated for *between 1 and 20 seconds* and released for an interval of *between 2 and 15 seconds* the pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid"

- claim 50 – "generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa), each pulse of negative pressure being generated for *between 1 and 20 seconds* and released for an interval of *between 2 and 15 seconds* the pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid"

As with independent claims 1, 25, 52, and 62 discussed above, the shortest negative pressure pulse covered by independent claims 48 and 50 is 3 seconds. As is discussed above, MacLeod teaches only shorter pressure pulses. Accordingly, for the same reasons set forth above in connection with independent claims 1, 25, 52, and 62, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of claims 48 and 50.

Moreover, for the same reasons set forth above in connection with dependent claims 29-30, 32-33, 54, 64-65, and 69-76, Applicants respectfully submit that the Final Office Action errs in asserting that negative pressure pulses of more specific duration as recited in dependent claims 49 and 51 would have been obvious in light of MacLeod. Dependent claims 49 and 51 both recite "wherein the negative pressure is generated for 10 seconds and then released for 7 seconds." For the reasons set forth above, Applicants submit that one skilled in the art would not have found the 17-second pressure pulses of dependent claims 49 and 51 to be an obvious extension of MacLeod. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of claims 49 and 51.

Claim 81 depends from claim 48, and claim 82 depends from claim 50. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of these claims for the reasons set forth above.

D. The Board Should Reverse the Final Office Action's Rejection of Claims 19-24 and 43 Because They Are Not Rendered Obvious by MacLeod in View of Grahn and Norton and further in view of U.S. Patent No. 3,896,794 to McGarath and U.S. Patent No. 4,186,732 to Christoffel.

Claims 19-24 depend from claim 1, and claim 43 depends from claim 25. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of these claims for the reasons set forth in Section A under the Argument Heading.

E. The Board Should Reverse the Final Office Action's Rejection of Claims 39-42 Because They Are Not Rendered Obvious by MacLeod in view of U.S. Patent No. 3,094,983 and further in view of Grahn.

Claims 39-42 depend from claim 25. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of these claims for the reasons set forth in Section A under the Argument Heading.

F. The Board Should Reverse the Final Office Action's Rejection of Claims 47 and 61 Because Norton Does Not Anticipate Them Under 35 U.S.C. § 102(b).

1. The Final Office Action's Rejection of Claim 61 Does Not Address the Language of Claim 61.

Applicants respectfully submit that the Final Office Action's explanation of the rejection of claim 61 bears no relation to the language of claim 61. Claim 61 is as

follows:

> A method of applying a pulsating negative pressure to a local region of the body, comprising:
> providing a pressure chamber containing a gas;
> introducing a limb into the pressure chamber such that the limb is sealed from external conditions;
> partially filling the pressure chamber with a liquid so that the limb is substantially surrounded by and in direct contact with the liquid while leaving a gas pocket above the liquid in an upper region of the chamber;
> *continuously supplying a constant negative pressure into the gas pocket; and*
> *introducing a positive pressure into the gas pocket for between 2 and 15 seconds to temporarily release negative pressure within the chamber and to temporarily produce a net positive pressure in the gas pocket.*

The Final Office Action (page 9) rejects claim 61 as being anticipated by Norton and offers only the following explanation:

> "Norton et al teaches a pressure chamber 31 (figure 6) into which the limb can be inserted, a barrier layer of flexible material 31 housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from a flow of liquid within the chamber, wherein the device includes an element or means for generating a pulsating pressure within the pressure chamber, and an element or means for generating a negative pressure between the barrier layer and the area of skin (figure 14) to maintain the barrier layer in contact with the area of skin. Note column 9, lines 63-68, and column 10, lines 1-21. Therefore, Norton et al 's device is capable of providing the recited pressures ."

As can be seen, the explanation does not address claim 61's method. For example, it does not address claim 61's "continuously supplying" or "introducing" steps. Accordingly, Applicants respectfully submit that the Final Office Action has not made a prima facie case that Norton anticipates claim 61.

Moreover, Applicants respectfully submit that claim 61 is patentable over Norton. Norton does not disclose either of claim 61's "continuously supplying" or "introducing"

steps. The specification of the present application describes benefits associated with these steps as follows:

> "When the pressure drops back to zero (relative to atmospheric pressure), the veins constrict and the blood is forced towards the direction with the lowest resistance to flow. The venous valves will effectively force the blood in the direction towards the heart only. If a positive pressure is added the transmurale pressure will drop. The intramural pressure is much larger in the arteries. This leads to a relative larger constriction of veins compared to arteries, and the veins are "emptied" of blood. The veins are now ready to receive more blood, and the pressure starts to drop again. The microvasculature capillaries also appear to be affected and there is also a possibility that the lymphatic system is affected too, and that lymph flow is increased. Lymphatic circulation is believed to be affected by the pulsating pressure in the same way as the veins because the vessels also have one-way valves. As the vessel walls are even thinner than in the veins, a system operating on the lymphatic system alone may be utilised by operating at lower pressures (including positive pressures) but following the same pulsating mode, thereby minimizing the effects on the arteries/veins (because increased blood flow can have a negative effect on oedema etc.)."

(Page 14, lines 18-25.) Accordingly, because claim 61 is patentable over Norton, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of claim 61.

2. *The Final Office Action's Rejection of Claim 47 Does Not Address Every Limitation of Claim 47.*

Applicants respectfully submit that the Final Office Action's rejection of claim 47 as anticipated by Norton is improper because it does not address every limitation of claim 47's device. Relevant portions of claim 47 are as follows:

> a barrier layer of flexible material housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from an outer region having a flow of

liquid within the chamber,
wherein the device includes
. . . .
an element or means for generating a negative pressure between the barrier layer and the area of skin to maintain the barrier layer in contact with the area of skin, *the element or means for generating negative pressure being in communication with the inner region but not with the outer region.*

The Final Office Action (page 9) explains its rejection of claim 47 as follows:

> "Norton et al teaches a pressure chamber 31 (figure 6) into which the limb can be inserted, a barrier layer of flexible material 31 housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from a flow of liquid within the chamber, wherein the device includes an element or means for generating a pulsating pressure within the pressure chamber, and an element or means for generating a negative pressure between the barrier layer and the area of skin (figure 14) to maintain the barrier layer in contact with the area of skin. Note column 9, lines 63-68, and column 10, lines 1-21. Therefore, Norton et al 's device is capable of providing the recited pressures ."

As can be seen, this explanation does not address the last limitation recited in claim 47—"the element or means for generating negative pressure being in communication with the inner region but not with the outer region." Thus, the Final Office Action does not make a prima facie case supporting the rejection of claim 47.

Moreover, Norton discloses nothing that can generate negative pressure by being in communication with an inner region but not with an outer region. Rather, Norton states,

> "Thus, a continuous suction can be created in the space between the limb and the sealed container by an external evacuation device. One method of achieving this is to enclose the legs and housing units of the system by a vacuum enclosure 84 as shown by the dashed line in FIG. 13 . . . ."

(Norton at 11:19-24.) Norton's vacuum enclosure (84 in FIG. 13) surrounds and is in

communication with the entire housing units rather than with only the space between the sealed container (90 in FIG. 14) and the patient's legs. Thus, Norton's device cannot anticipate amended claim 47. Moreover, such an enclosure that encapsulates the entire housing units would be unwieldy compared with a relatively smaller element or means in communication with the inner region but not with the outer region.

Norton also discloses two other ways to maintain a seal between the sealed container and the patient's limb, neither of which anticipate, or render obvious, amended claim 47. First, Norton states,

> "Such seal can be maintained by the use of an adhesive compound on the surface of the sealed container between the container and the limb. However, such a method may be impractical or inappropriate in many situations."

(Norton 11:8-11.) Amended claim 47 is clearly patentable over such a device that uses adhesive to create a seal. Second, Norton discloses a "self-evacuation system" (see FIG. 14) in which the mechanism that produces the pressure cycle also expels air from between the sealed enclosure and the leg. (*Id.* at 11:29-12:6.) Amended claim 47 is patentable over this device in that amended claim 47 includes a separate element or means for maintaining the barrier layer in contact with the area of skin. For these reasons, Applicants respectfully submit that amended claim 47 is both novel and nonobvious over Norton. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of claim 47.

G. Conclusion

Based on the foregoing, the Board should reverse the rejection of claims 1-27, 29-30, 32-43, 47-52, 54-58, 60-67, and 69-82. This Appeal Brief sets forth reasons why the

rejection of claims 1, 25, 29-30, 32-33, 47-52, 54, 61-62, 64-65, and 69-76 should be reversed. Applicants also respectfully submit that claims 2-24, 26-27, 34-43, 55-58, 60, 63, 66-67, and 77-82 should be reversed because they depend from allowable claims.

Respectfully submitted,

Dated: June 23, 2008

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CLAIMS APPENDIX

1. A device for applying a pulsating pressure to a local region of the body, the device comprising a pressure chamber in to which a limb of the body can be placed to seal it from external conditions, whereby in use the limb can be immersed in a liquid contained in the pressure chamber such that the liquid surrounds and is in contact with the limb wherein an element is provided to generate pulses of negative pressure within the chamber that can be transmitted to the limb directly via the liquid, the element being adapted to generate negative pressure for between 1 and 20 seconds and to release negative pressure for between 2 and 15 seconds.

2. The device as claimed in claim 1, wherein the pressure chamber comprises an elongate housing having an opening for receiving the limb and a seal arranged around the opening for sealing against the limb.

3. The device as claimed in claim 2, wherein the elongate housing is a cylindrical or box-shaped housing.

4. The device as claimed in claim 2, wherein an inlet and outlet are provided in the housing for introducing and discharging the liquid into and out of the chamber.

5. The device as claimed in claim 4, wherein the inlet and outlet are in communication with each other via a fluid path that is defined by internal walls of the chamber and the surface of the limb once it has been introduced into the chamber, such

that in use liquid flows from the inlet into the chamber, circulates around and in contact with the surface of the limb and is then discharged via the outlet.

6. The device as claimed in claim 4, wherein a liquid flow transmission means is connected to the pressure chamber via the inlet and outlet to generate a flow of liquid which is circulated within the chamber and around the limb.

7. The device of claim 6, wherein the flow transmission means is a pump.

8. The device as claimed in claim 6, wherein the flow transmission means is connected to the pressure chamber via the inlet and outlet to generate a flow of liquid which is circulated within the chamber and around the limb.

9. The device as claimed in claim 1, wherein the liquid is circulated through a heat exchanger unit before it enters the pressure chamber to control the temperature of the liquid.

10. The device as claimed in claim 9, wherein the heat exchanger unit comprises a plurality of heat exchanger tubes housed within a water bath.

11. The device as claimed in claim 1, wherein the element comprises a pulsating means for generating pulses of pressure within the chamber.

12. The device as claimed in claim 4, wherein the element comprises a pulsating means for generating pulses of pressure within the chamber.

13. The device as claimed in claim 6, wherein the element comprises a pulsating means for generating pulses of pressure within the chamber.

14. The device as claimed in claim 9, wherein the element comprises a pulsating means for generating pulses of pressure within the chamber.

15. The device as claimed in claim 1, wherein the element comprises one or more connections that are provided in an upper region of the pressure chamber, coupled via a Y-connector, to communicate the chamber with a pressure source which is at a pressure different from atmospheric pressure for regulating the pressure within the chamber.

16. The device as claimed in claim 15, wherein said pressure source is a suction device.

17. The device as claimed in claim 16, wherein said pressure source is set to create a negative pressure of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa).

18. The device as claimed in claim 17, wherein a valve is provided in

connection with the pressure chamber to bleed air at intervals into the pressure chamber to thereby generate the pulses of negative pressure.

19. The device as claimed in claim 18, wherein the valve is controlled by a timer system to bleed air into the pressure chamber for between 2 and 15 seconds at a time.

20. The device as claimed in claim 19, wherein the valve is controlled by a timer system to bleed air into the pressure chamber for between 5 and 10 seconds at a time.

21. The device as claimed in claim 20, wherein the valve is controlled by a timer system to bleed air into the pressure chamber for 7 seconds at a time.

22. The device as claimed in claim 18, wherein the valve is controlled by the timer system to be closed for between 1 and 20 seconds at a time to allow build up of negative pressure.

23. The device as claimed in claim 22, wherein the valve is controlled by the timer system to be closed for between 5 and 15 seconds at a time to allow build up of negative pressure.

24. A device as claimed in claim 18, wherein the valve is controlled by the

timer system to be closed for 10 seconds at a time to allow build up of negative pressure.

25. A method of applying a pulsating pressure to a local region of the body comprising the steps of:

providing a pressure chamber;

introducing a limb in to the pressure chamber such that it is sealed from external conditions;

filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid; and

generating a pulsating negative pressure within the chamber and transmitting the pulses of negative pressure to the limb directly via the liquid, wherein each pulse of negative pressure is generated for between 1 and 20 seconds and released for between 2 and 15 seconds.

26. The method as claimed in claim 25, wherein pulses of negative pressure of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa) are generated within the pressure chamber.

27. The method as claimed in claim 26, wherein pulses of negative pressure of -40 mmHg (-5.3 kPa) are generated within the pressure chamber.

29. The method as claimed in claim 25, wherein each pulse of negative pressure is generated for between 5 and 15 seconds.

30. The method as claimed in claim 29, wherein each pulse of negative pressure is generated for 10 seconds.

32. The method as claimed in claim 29, wherein the negative pressure is released for an interval of between 5 and 10 seconds at a time to create the pulses of negative pressure.

33. The method as claimed in claim 30, wherein the negative pressure is released for 7 seconds at a time to create the pulses of negative pressure.

34. The method as claimed in claim 25, wherein the liquid is circulated within the pressure chamber to generate a flow of liquid which is in direct contact with the limb.

35. The method as claimed in claim 26, wherein the liquid is circulated within the pressure chamber to generate a flow of liquid which is in direct contact with the limb.

36. The method as claimed in claim 29, wherein the liquid is circulated within the pressure chamber to generate a flow of liquid which is in direct contact with the limb.

37. The method as claimed in claim 32, wherein the liquid is circulated within the pressure chamber to generate a flow of liquid which is in direct contact with the limb.

38. The method as claimed in claim 25, wherein the temperature of the liquid is controlled by a heat exchanger unit to be at a temperature either above or below the core body temperature of the patient.

39. The method as claimed in claim 38, wherein the liquid is maintained at a temperature of less than 30°C whilst the pulsating pressure is applied to the limb.

40. The method as claimed in claim 39, wherein the liquid is maintained at a temperature of less than 10°C whilst the pulsating pressure is applied to the limb.

41. The method as claimed in claim 38, wherein the liquid is maintained at a temperature greater than 43.5°C whilst the pulsating pressure is applied to the limb.

42. The method as claimed in claim 41, wherein the liquid is maintained at a temperature greater than 45°C whilst the pulsating pressure is applied to the limb.

43. The method as claimed in claim 24, wherein said method is being applied to the limb of the patient to control or regulate the temperature of the patient.

47. A device for applying a pulsating pressure to an area of skin on a limb of a body comprising

a pressure chamber into which the limb can be inserted,

a barrier layer of flexible material housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from an outer region having a flow of liquid within the chamber,

wherein the device includes

an element or means for generating a pulsating negative pressure within the pressure chamber, and

an element or means for generating a negative pressure between the barrier layer and the area of skin to maintain the barrier layer in contact with the area of skin, the element or means for generating negative pressure being in communication with the inner region but not with the outer region.

48. A method of treating hypothermia in a human body by applying a pulsating pressure to a local region of that body comprising the steps of:

providing a pressure chamber;

introducing a limb in to the pressure, chamber such that it is sealed from external conditions;

filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid;

circulating the liquid via a heat exchanger unit to heat the liquid to a temperature

of 40°C or above; and

generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa), each pulse of negative pressure being generated for between 1 and 20 seconds and released for an interval of between 2 and 15 seconds the pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid.

49. The method of treating hypothermia in a human body as claimed in claim 48, wherein the negative pressure is generated for 10 seconds and then released for 7 seconds.

50. A method of treating hyperthermia in a human body by applying a pulsating pressure to a local region of that body comprising the steps of:

providing a pressure chamber;

introducing a limb in to the pressure, chamber such that it is sealed from external conditions;

filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid;

circulating the liquid via a heat exchanger unit to cool the liquid to a temperature of 30°C or less; and

generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa), each pulse of negative pressure being

generated for between 1 and 20 seconds and released for an interval of between 2 and 15 seconds the pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid.

51. The method of treating hyperthermia in a human body as claimed in claim 50, wherein the negative pressure is generated for 10 seconds and then released for 7 seconds.

52. A method of increasing blood flow to a local region of the body, comprising:

providing a pressure chamber;

introducing the local region of the body into the pressure chamber such that the local region is sealed from external conditions;

introducing liquid into the pressure chamber so that the local region of the body is substantially surrounded by and in direct contact with the liquid; and

alternately generating negative pressure for a predetermined time interval of 1 to 20 seconds and releasing negative pressure for a predetermined time interval of 2 to 15 seconds within the chamber, the negative pressure being transmitted to the local region through direct contact with the liquid.

54. The method of claim 52, wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative

pressure for a time interval of about 10 seconds and releasing the negative pressure for a time interval of about 7 seconds.

55. The method of claim 52, wherein the alternately generating and releasing pulses of negative pressure within the chamber comprises alternately generating a negative pressure between about -20mmHg and -80mmHg and releasing the negative pressure.

56. The method of claim 55, wherein the alternately generating and releasing pulses of negative pressure within the chamber comprises alternately generating a negative pressure of about -40mmHg and releasing the negative pressure.

57. The method of claim 52, wherein the introducing liquid into the pressure chamber comprises introducing liquid having a temperature different than the core body temperature.

58. The method of claim 52, further comprising the step of circulating the liquid around the surfaces of the local region of the body to transfer heat to or from the local region.

60. The method of claims 52, wherein the local region is a limb.

61. A method of applying a pulsating negative pressure to a local region of the

body, comprising:

providing a pressure chamber containing a gas;

introducing a limb into the pressure chamber such that the limb is sealed from external conditions;

partially filling the pressure chamber with a liquid so that the limb is substantially surrounded by and in direct contact with the liquid while leaving a gas pocket above the liquid in an upper region of the chamber;

continuously supplying a constant negative pressure into the gas pocket; and

introducing a positive pressure into the gas pocket for between 2 and 15 seconds to temporarily release negative pressure within the chamber and to temporarily produce a net positive pressure in the gas pocket.

62. A method of transferring thermal energy to and from a body, comprising:

providing an enclosure;

introducing a limb into the enclosure such that the limb is sealed from external conditions;

introducing thermal exchange liquid into the chamber so that the limb is completely surrounded by and in direct contact with the liquid, the introduced thermal exchange liquid having a predetermined temperature different than the core body temperature;

circulating the introduced thermal exchange liquid around the surfaces of the limb, the liquid transmitting heat to or from the limb; and

generating a pulsating negative pressure within the enclosure, the pulsating

negative pressure being transmitted to the limb through direct contact with the thermal exchange liquid, wherein generating pulsating negative pressure includes alternately generating negative pressure for between 1 and 20 seconds and releasing negative pressure for between 2 and 15 seconds.

63. The method of claim 62, wherein generating the pulsating pressure comprises alternately generating and releasing a negative pressure within the enclosure.

64. The method of claim 63, wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative pressure for a time interval of between about 5 and 15 seconds and releasing the negative pressure for a time interval of between about 5 and 10 seconds.

65. The method of claim 64, wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative pressure for a time interval of about 10 seconds and releasing the negative pressure for a time interval of about 7 seconds.

66. The method of claim 62, wherein the alternately generating and releasing pulses of negative pressure within the chamber comprises alternately generating a negative pressure between about -20mmHg and -80mmHg and releasing the negative pressure.

67. The method of claim 66, wherein the alternately generating and releasing pulses of negative pressure within the chamber comprises alternately generating a negative pressure of about -40mmHg and releasing the negative pressure.

69. The device as claimed in claim 1, wherein the element is adapted to release negative pressure for between 5 and 10 seconds.

70. The device as claimed in claim 1, wherein the element is adapted to release negative pressure for 7 seconds.

71. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for between 5 and 15 seconds.

72. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for 10 seconds.

73. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for between 5 and 15 seconds and to release negative pressure for between 5 and 10 seconds.

74. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for between 5 and 15 seconds and to release negative pressure for 7 seconds.

75. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for 10 seconds and to release negative pressure for between 5 and 10 seconds.

76. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for 10 seconds and to release negative pressure for 7 seconds.

77. The device as claimed in claim 1, wherein the liquid is water.

78. The device as claimed in claim 16, wherein said suction device is a vacuum pump or vacuum line.

79. The device as claimed in claim 17, wherein said pressure source is set to create a negative pressure of -40 mmHg (-5.3 kPa).

80. The device as claimed in claim 18, wherein the valve is provided between said chamber and said pressure source.

81. The method of treating hypothermia in a human body as claimed in claim 48, wherein said pulses of negative pressure within the chamber are -40 mmHg (-5.3 kPa).

82. The method of treating hyperthermia in a human body as claimed in claim 50, wherein the pulses of negative pressure within the chamber are -40 mmHg (-5.3 kPa).

EVIDENCE APPENDIX

1. U.S. Patent No. 3,292,613 to MacLeod, first cited by Examiner in an Office Action dated June 14, 2006.

2. U.S. Patent No. 3,094,983 to MacLeod, first cited by Examiner in an Office Action dated June 14, 2006.

3. U.S. Patent No. 5,683,438 to Grahn, first cited by Examiner in an Office Action dated June 14, 2006.

4. U.S. Patent No. 3,878,839 to Norton et al., first cited by Examiner in an Office Action dated June 14, 2006.

5. U.S. Patent No. 3,896,794 to McGarath, first cited by Examiner in an Office Action dated June 14, 2006.

6. U.S. Patent No. 4,186,732 to Christoffel, first cited by Examiner in an Office Action dated June 14, 2006.

7. Rule 1.132 Affidavit of Erling Bekkestad Rein submitted on February 15, 2007.

Dec. 20, 1966 N. A. MacLEOD 3,292,613

MEANS AND METHOD FOR CONTROLLED PULSATORY FLOW OF BLOOD TO IMPROVE CIRCULATION

Filed June 21, 1963 2 Sheets-Sheet 1

Fig. 1.

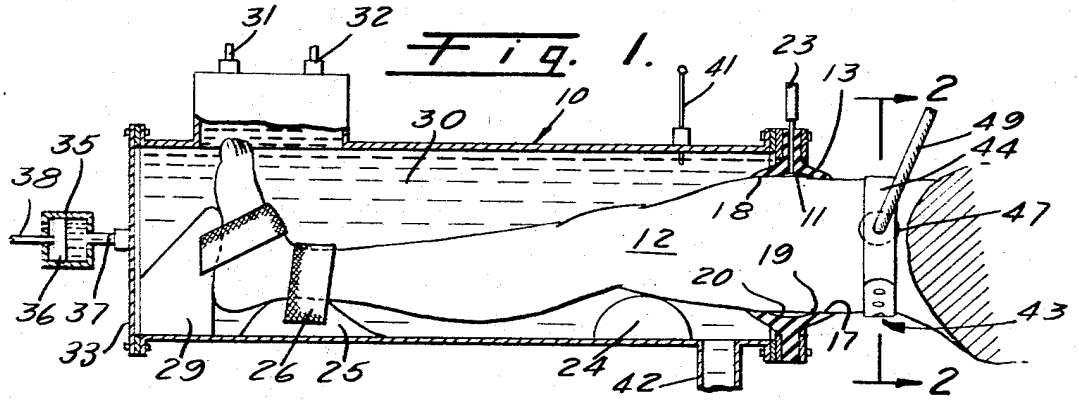


Fig. 2.

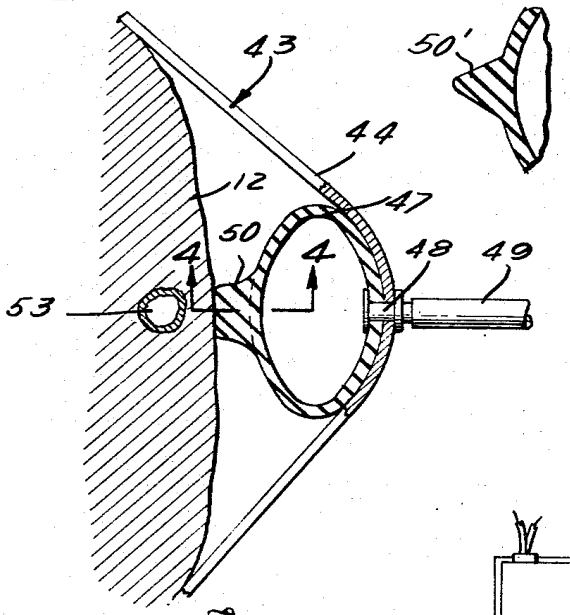


Fig. 4.

Fig. 3.

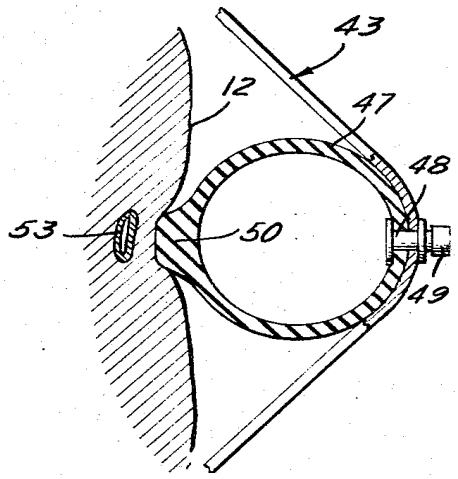


Fig. 5.

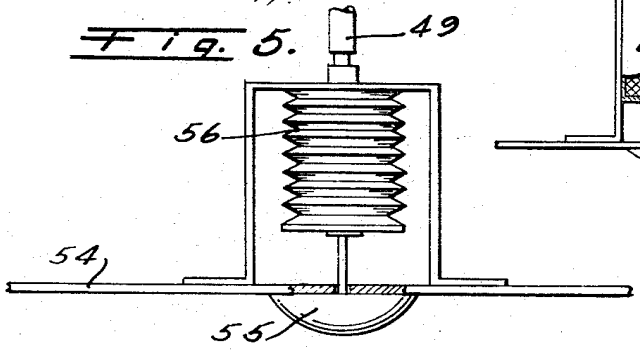
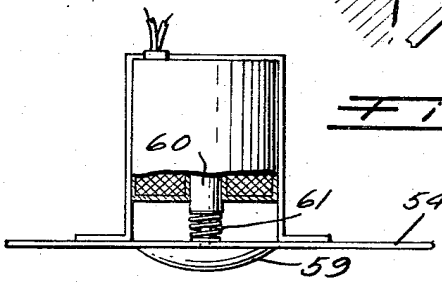


Fig. 6.



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MEANS AND METHOD FOR CONTROLLED PULSATORY FLOW OF BLOOD TO IMPROVE CIRCULATION

Filed June 21, 1963 2 Sheets-Sheet 2

Fig. 7.

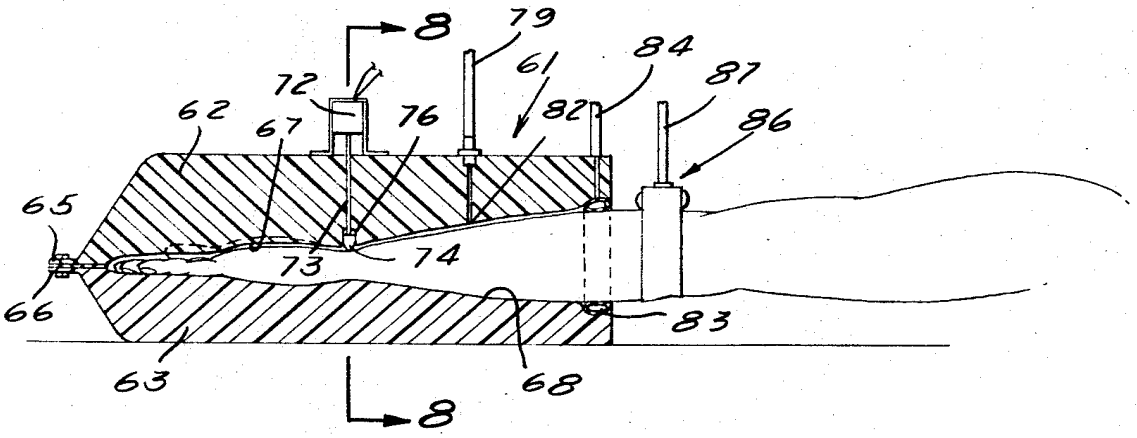
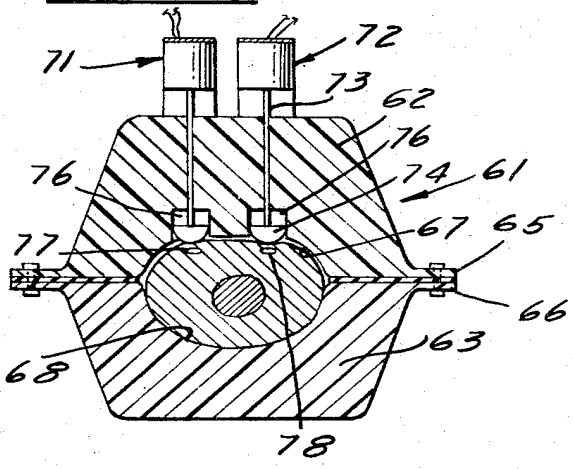


Fig. 8



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United States Patent Office 3,292,613 Patented Dec. 20, 1966

3,292,613

MEANS AND METHOD FOR CONTROLLED PULSATORY FLOW OF BLOOD TO IMPROVE CIRCULATION

Norman A. MacLeod, La Habra, Calif., assignor of thirty-six percent to R. Welton Whann, Los Angeles, Calif., eighteen percent to Wilbur A. Selle, Los Angeles, Calif., and ten percent to Frank F. Reed, Pasadena, Calif.

Filed June 21, 1963, Ser. No. 289,653
16 Claims. (Cl. 128—40)

This is a copending application of one which issued as United States Patent No. 3,094,983 for Blood Circulation Device and Method on June 25, 1963.

This invention relates to a method and apparatus for improving the circulation of fluids within parts of a human body or an animal and, more particularly, is for the purpose of improving blood circulation in a human body or in that of an animal.

When blood is pulsed from the heart into the arteries, the blood discharge valves of the heart close, and the pressure impulse in the blood is absorbed by the arterial flow and by the distention of the elastic walls of the arteries. The distention of the arteries tends to maintain a more uniform blood flow to the arterioles and from them to the capillary bed. The return flow from the capillaries through the veins to the heart is a much more steady one than in the arteries and it is subject to control against back flow by a series of check valves in the veins.

As described in my above patent, it is clear that variations of pressure applied to a limb or any other part of the body act differently on the venous flow than on the arterial flow. In the veins, a negative pressure application to a limb which would tend to draw blood away from the heart cannot do so because of the check valves in the veins, and a positive pressure application tends to squeeze the veins, open the venous valves, and force the blood to the heart. However, in the arteries, applications of negative and positive pressures tend to cause surging of the blood toward and away from the heart.

According to the invention, I have found that much greater stimulation of blood circulation is possible when the arterial surge toward the heart, on application of a positive pressure, is reduced or stopped entirely. That is, when there is a localized pressure applied at the well-known arterial pressure points, at which pressure can be applied from the skin surface, the arterial flow is greatly reduced or even entirely stopped downstream of the localized pressure points in the direction away from the heart. Actually, at any point where arterial pulsing can be felt, pressure can be applied to occlude an artery.

My method for greatly increasing the stimulation of blood circulation includes the enclosing in a chamber of a part of a body, such as a leg, and applying a positive pressure pulse within the chamber and at the same time applying a localized pressure at the appropriate arterial pressure point, this latter pressure being maintained during the period of the positive pressure pulse within the chamber and preferably for a relatively short period therebefore and thereafter. The foregoing steps prevent the flow of blood toward the heart in the artery in question and force the flow away from the part in the chamber into the capillaries and veins and back to the heart.

When a larger portion of the body, for example, that part from the waist down, is sealed within a variable pressure chamber, the localized pressure means on individual arteries are enclosed within the chamber and are operable from the exterior thereof.

According to the invention, consistent with the foregoing, when a negative pressure pulse is applied to a part of a body within a variable pressure chamber to tend to

pull arterial blood from the heart, the checking action of the valves in the veins can be assisted by applying localized pressures on the major veins which are found near the surface of the body. By this method, blood flow in the enclosed body portion can be made greater than that under conditions of violent exercise, but without any strain upon the heart.

In the practice of this method, it is not necessary to synchronize pressure variation with the heart action, but when such synchronization is desired, the occlusion of the artery should preferably occur when the heart is not pumping to the artery, that is, when the arterial pressure is the lowest, and the occluding pressure should be relaxed when the arterial pulse is at its peak pressure so that the blood can flow into the encased body part.

Localized pressure points, where arterial occlusion by indentation of the skin can be produced, are, for example, on the femoral artery which supplies most of the blood to the leg, on the popliteal artery at the back of the knee, on the posterior tibial artery at the ankle, and on the brachial artery in the arm. The brachial vein is adjacent to the latter artery and some venous occlusion results from brachial artery occlusion, but the deep-seated axillary vein in the upper arm cannot be occluded. A similar situation obtains in the leg in regard to hte juxtaposition of the femoral artery and femoral vein and venous flow through other deep-seated veins. At the wrist, both the radial and ulnar arteries can be readily occluded. In certain serious failure of leg or arm circulation, superficial surgery can be performed to make the femoral artery of the leg and the branchial artery of the arm more available for occlusion pressures.

As pressures of 2 to 10 pounds per square inch, or 150 to 500 millimeters of mercury, can be safely applied, a very positive blood circulation can be induced. In terms of regeneration of limb functions, this is most important and has considerable therapeutic value in such diseases as arthritis, traumatic injuries, and all forms of peripheral vascular disease.

The use of liquid in a variable pressure chamber to apply pressure pulses on a part of a body is preferable to gas because of the non-compressibility of the liquid, but it is more difficult to handle. However, it has been found that when the chambers are so shaped to closely conform with the part of the body inserted therein so as to eliminate excess volume in which a gas can be compressed or expanded by pressure variation within the chamber, a gas can be used effectively as the medium for applying the pressure pulses when the arterial occlusion method is used. That is, in the use of a gas, for practical purposes, air, the volume in the chamber around the body portion therein must be reduced as much as possible and this can be done with non-porous pads. Even so, however, in the use of a gas, as compared with a liquid, the pressure-time curve cannot be as steep and the negative and positive pressures cannot be cycled as quickly.

Accordingly, it is an object of the present invention to provide an improved method and an improved apparatus for increasing blood circulation.

It is another object of the present invention to provide a method and means to provide positive pressure pulses to a part of a human body or an animal while an artery or arteries to the part are occluded.

It is still another object of the present invention to provide means and a method for applying negative pressures to a part of a body while a major vein or veins are occluded to assist the check valves in the veins. In elderly persons and in certain diseases, the check valves in the veins are inefficient and, therefore, the occlusion of the veins during negative pressure impulses inhibits back flow into the veins and greatly increases positive blood

flow into the body part. This is especially effective when the occlusion of the vein is associated with the use of arterial occluding means during the period of rising pressure from a minimum negative to a positive pressure, the latter arterial occluding means being applied during the entire period of positive pressure.

It is a further object of the present invention to provide an improved method and apparatus for increasing blood circulation in a limb, for example, and which will eliminate distention of the arteries of the limb outside of the chamber and between the chamber sealing means and the heart during positive pressure pulses within the chamber. This elimination of distention of the arteries outside the chamber results from the occlusion of the artery or arteries in question during the positive pressure pulse.

It is a still further object of the present invention to provide an improved method and apparatus by which a very considerable positive pressure gradient can be created from an artery in an enclosed limb, and through the capillaries to the veins.

It is another object of the invention to provide an improved method and means for applying a localized pressure on near-surface arteries to inhibit arterial flow and at the same time apply a positive pressure pulse to that portion of the body downstream of the point of the localized pressure so that the positive pressure pulse is more usefully employed in forcing blood from the arteries and arterioles into the capillaries and from the capillaries into the veins than has heretofore been experienced.

Further objects and advantages of the invention may be brought out in the following part of the specification wherein small details have been described for the competence of disclosure, without intending to limit the scope of the invention which is set forth in the appended claims.

Referring to the accompanying drawings, which are for illustrative purposes only:

FIG. 1 is a side elevational view, partially in cross section, of an apparatus according to the present invention;

FIG. 2 is a cross sectional view of an artery occluding device, taken as indicated by the line 2—2 in FIG. 1;

FIG. 3 illustrates the occluding device in FIG. 2 in operation;

FIG. 4 is a fragmentary, cross sectional view of an occluding device having a relatively pointed contacting part;

FIG. 5 is a fragmentary, cross sectional view of another embodiment of an occluding device;

FIG. 6 is a fragmentary, cross sectional view of a solenoid-operated occluding means;

FIG. 7 is a side elevational view, partially in cross section, of another embodiment of the invention; and

FIG. 8 is a cross sectional view, taken as indicated by the line 8—8 in FIG. 7.

Referring again to the drawings, in FIG. 1, there is shown an elongated chamber **10**, having an open end **11** and having a cross section suitable to receive a substantial portion of a human leg **12**. At the open end there is a seal **13**, having its outer periphery adapted to be secured to a flange on the chamber and having its inner periphery **17** substantially annular to conform to the periphery of the leg **12**. The inner periphery of the seal has two lips **18** and **19**, spaced by an enlarged diameter surface **20**. The seal is maintained by a negative pressure made available through a tube **23**, terminating inwardly through the surface **20** so that the negative pressure draws the skin of the leg against the surfaces of the lips **18** and **19** and toward the surface **20**, a greater pressure at all times being exerted on the exterior surfaces of the seal to force it into sealing relationship with the leg.

The leg is shown to be resting within the chamber **10** on hard rubber cushions or blocks **24** and **25** and it is

secured to the latter block by a strap **26**. The foot is also strapped to a block **29**, in turn secured to the chamber, so as to tend to hold the foot in the position shown. The straps may be secured to the foot and ankle through a removable access flange **33**.

The chamber **10** is adapted to be completely filled with a liquid **30**, such as water, as disclosed in the above-mentioned copending application. It may be filled through a fitting **31** and vented, while filling, through a fitting **32** to which a pressure gauge may be attached after the chamber is completely filled.

At the left end of the chamber in the drawing, there is a cylinder **35** having a reciprocating piston **36** therein. One end of the cylinder is connected to the chamber by a tube **37** so that movement of the piston **36** will change the pressure within the filled chamber. Through the other end of the cylinder extends a piston rod **38**, connected to the piston **36**, and which may be reciprocated to move the piston by conventional means. The piston can be adjusted to have a starting position, either with a zero gauge pressure or a constant positive or negative pressure, and any movement of the piston will then increase or decrease the pressure in the chamber. Adjacent the other end of the chamber is a thermometer **41** fitted within the chamber to indicate the temperature of the liquid. In the lower portion of the drawing is a sealable drain **42**.

In FIGS. 1–3, there is shown an artery occluding device, generally designated as **43**, secured to the leg by a strap **44**. A generally spheroidal-shaped ball **47** is fitted between the strap and the leg, being secured to the strap by a flanged tube **48** having an opening into the ball and having its outer end connected to a gas or liquid pressure tube source **49**. The ball is made of plastic flexible material so as to be inflatable, and has a relatively hard projection **50** in abutment with the leg surface, immediately outwardly, in this case, of the femoral artery **53**.

In FIG. 2, the ball **47** is shown deflated or substantially compressed by the strap **44** around the leg and the artery **53** is shown to be open. In FIG. 3, the ball **47** has been inflated with pressure through the source **49** so as to exert considerable pressure on the leg so as to close or substantially close the artery **53**.

In FIG. 4, there is shown a ball equivalent to ball **47**, having a more pointed projection **50'** which, for example, is adaptable for use on the radial and ulnar arteries in the wrist. In FIG. 5, there is shown an artery or vein occluding device secured to a strap **54**, equivalent to strap **44**. Here, the projection **55** for occluding the artery or vein is connected by a rod to a pressure extensible bellows **56** which in turn is connected to a pressure source **49**. When the pressure is increased within the bellows from the source **49**, the projection **55**, as indicated in FIG. 3, moves against the skin so as to occlude the blood-carrying member.

In FIG. 6, there is shown another embodiment of an occluding device secured to a strap **54'** and having a projecting member **59**, connected to a solenoid core **60** by a rod surrounded by a coil spring **61**. The spring acts to hold the projecting member in its retracted position and when the solenoid is energized, the core is moved against the spring so as to move the projecting member **59** into its extended position against the skin so as to occlude the blood carrying member.

The device shown in FIG. 1 can be operated in a number of different ways and with many variations in pressure. For example, a positive pressure can be exerted on the leg **12** by means of moving the piston **36** inwardly toward the chamber and just before the positive pressure is applied, the ball **47** can be energized by pressure from the source **49** so as to be expanded, as shown in FIG. 3, to occlude the artery **53**. By occluding the femoral artery and applying pressure to the leg, the blood is forced through the artery downstream of the occluding device **43** and is further forced through the capillaries and the veins in a manner to greatly exceed the normal flow, especially where

the circulation is poor. The indenting pressure on the artery should ordinarily be maintained during the entire positive pressure application to the chamber. Then, when a negative pressure is applied by moving the piston **36** away from the chamber, the pressure on the artery is released, as indicated in FIG. 2, and the blood is caused to flow into the artery at a much greater rate than under normal conditions.

The pressure can be synchronized to the heart beat or can be applied less or more frequently and in regular multiples of a heart beat, for example, during every second or third heart beat, or two, three, or four times during each heart beat, or the pressure can be applied irregularly with respect to the heart beat. Further, where synchronization with the heart is desired, the occlusion of the artery should preferably occur when the heart is not pumping to it, that is, when the arterial pressure is the lowest, and the occluding pressure should be relaxed when the arterial pulse is at a peak pressure so that the blood can readily flow into the encased limb.

When a positive pressure is applied to the chamber, the limb or leg, as shown, tends to move out of the chamber, and thus, the straps are applied to the ankle and foot to prevent the latter from moving and to restrict the outward movement of the leg.

Where the check valves in the veins are inefficient, a major vein can be occluded during the negative pressure application in the chamber so that the negative pressure will not tend to draw blood through the veins in the wrong direction, and this will permit the negative pressure to act upon the arterial flow from the heart so that it will be at a maximum into the limb.

As previously indicated, a liquid is the preferable medium for applying rapid pressure changes to a part of a body, but it has the disadvantage that it has to be handled. A gas, such as air, of course, does not have such a disadvantage but because it is compressible, it is not as good a medium as liquid to apply rapid pressure changes to a limb. However, when a gas in a chamber is restricted to a very small volume surrounding a limb and a relatively large piston displacement is involved for producing pressure variation, there is not much difficulty in compression or expansion of the gas and the pressure can be adequately applied to a limb with air.

An apparatus, as shown in FIGS. 7 and 8, for use of air as the pressure-applying medium is particularly useful in stimulating blood flow in the hand. An air chamber **61** is formed between upper and lower molded plastic parts **62** and **63**, sealingly secured together at their flanges **65** and **66**. The upper part **62** has an inner molded surface **67** to conform to the inner parts of a hand and forearm and the lower part **63** has an inner surface **68** to conform to the outer parts of the hand and forearm. The arrangement shown permits only a minimum of air in the chamber between the arm and hand surfaces and the surfaces of the chamber. If, for example, there would be excess space between the hand and the chamber, nonporous plastic material could be inserted on the arm and hand to reduce the air volume.

In this embodiment, solenoid-operated occluding devices, similar to the type shown in FIG. 6, are used at the wrist to occlude the radial and ulnar arteries. Here, as distinct from the structure shown in FIG. 1, the artery occluding means is within the chamber, rather than externally thereof. However, in either type of chamber, the artery occluding means may be externally or internally of the chamber.

The artery occluding devices **71** and **72** have rods **73** connecting the solenoid cores with the projecting plungers **74** which are slidably engaged in recesses **76** in the upper part of the chamber **62**. As shown in FIG. 8, the projecting plungers **74** are shown in their non-extended positions having a tight fit on the wrist so that when the solenoids are energized, the two plungers **74** move downwardly to occlude the wrist arteries **77** and **78**.

In FIG. 7, a chamber pressure source **79** extends from a variable pressure means, such as a negative and positive pressure varying air pump, not shown, but equivalent in effect to the cylinder and piston **35** and **36**, respectively, in FIG. 1, and terminates at its inner end **82** in the chamber formed by the surfaces **67** and **68**, adjacent the arm.

At the opening of the chamber, there is a generally annular pressure seal **83**, adapted to be tightened within the chamber opening and on the arm by a liquid or fluid pressure supplied through a tube **84**.

Externally of the chamber on the arm is a vein occluding device **86**, equivalent to the artery occluding device **43**, shown in FIGS. 1, 2 and 3, the device **86** being strapped to the arm and being actuated by a fluid pressure through a tube **87**.

The operation of the chamber, shown in FIGS. 7 and 8, is substantially the same as that shown in FIG. 1. However, with air as the medium to apply the pressure variations to the limb, the pressure-time curve cannot be as sharp and the cycling of the pressure variation cannot be as fast as with liquid.

Since circulation problems are more severe in the arm below the wrist than above the wrist, and because of the convenient location of the radial and ulnar arteries, it is considered advantageous to occlude them at the wrist, as shown in FIGS. 7 and 8. Thus, when the high pressure is applied from the source **79** to the chamber and arm and just prior thereto, the solenoids in the devices **71** and **72** are energized to occlude the arteries. The pressure will then force the blood into the hand so that it can return to the heart through the veins. According to the cycle, when the negative pressure is applied from the source **79**, the solenoids in the devices **71** and **72** are deenergized and the rods **73** are retracted by means of springs, not shown, so that the arteries at the wrist are opened. At this time, the blood is free to flow into the arm and hand from the arteries, and in cases where the vein check valves need assistance, the vein occluding device **86** is actuated by the application of pressure through the tube **87**. This prevents blood from being drawn into the arm and hand through an improperly operating check valve in the vein and the flow is thus, then into the arm and hand from the arteries in a greater than normal amount due to the negative pressure on the limb, and there is no blood drawn into the arm and hand, in the wrong direction, through the vein.

It should be noted that in certain serious failures of leg or arm circulation, such as occurs during gangrene, surgery can be performed to make the femoral artery of the leg or the brachial artery of the arm available for the application of occlusion pressures in accordance with the invention.

The invention and its attendant advantages will be understood from the foregoing description and it will be apparent that various changes may be made in the form, construction and arrangement of the parts of the invention without departing from the spirit and scope thereof or sacrificing its material advantages, the arrangement hereinbefore described being merely by way of example. I do not wish to be restricted to the specific form shown or uses mentioned, except as defined in the accompanying claims, wherein various portions have been separated for clarity of reading and not for emphasis.

I claim:

1. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:

(a) applying a pressure pulse to a part of a body to affect the flow in an artery in said part; and

(b) applying localized pressure to said artery between a portion of said part and the heart to inhibit reverse arterial flow toward the heart during said pressure pulse.

2. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:
(a) applying a pressure pulse to a part of a body to affect the downstream blood flow in said part; and
(b) applying localized pressure to a near-surface artery to said part between a portion of said part and the heart to inhibit reverse arterial flow toward the heart during said pressure pulse.

3. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:
(a) applying negative pressure pulses ambient and to a part of a body to tend to pull arterial blood from the heart and through said part; and
(b) applying localized pressure adjacent said part on a near-surface vein during said pulses to assist the action of the vein check valves.

4. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:
(a) enclosing a part of a body to be treated in a chamber;
(b) sealing said part in said chamber;
(c) filling said sealed chamber with liquid;
(d) varying the pressure of all of said liquid alternately positively and negatively a predetermined amount at a predetermined rate; and
(e) applying pressure to an artery to said part upstream of a portion of said part to be affected by said varied pressures to inhibit arterial flow from said portion toward the heart during the periods the varied pressures applied are positive.

5. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:
(a) enclosing a part of a body to be treated in a chamber;
(b) sealing said part in said chamber;
(c) filling said sealed chamber with liquid;
(d) applying negative pressure pulses to all of said liquid to tend to pull arterial blood from the heart; and
(e) applying localized pressure on a near-surface vein downstream of a portion of said part to be affected by said negative pulses during the period said pulses are applied to assist the action of the vein check valves.

6. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:
(a) enclosing a part of a body to be treated in a chamber;
(b) sealing said part in said chamber without substantially affecting the circulation in said part;
(c) filling said sealed chamber with liquid;
(d) applying alternate negative and positive pressure pulses to all of said liquid;
(e) applying localized pressure during said positive pulses on said body adjacent said part to an artery extending in said part to inhibit arterial flow from said part toward the heart; and
(f) applying localized pressure to a vein adjacent said part during said negative pulses.

7. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:
(a) applying alternate negative and positive pressure pulses ambient and to a part of a body;
(b) applying localized pressure to a vein adjacent said part during said negative pulses; and
(c) applying localized pressure on said body adjacent said part to an artery extending into said part to inhibit arterial flow from said part toward the heart during said positive pulses.

8. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:
(a) enclosing a part of a body to be treated in a chamber;
(b) said chamber conforming to the shape of said part therein and the interior surfaces of said chamber being in juxtaposition with corresponding surfaces of said part;
(c) sealing said part in said chamber without substantially affecting the circulation in said part;
(d) filling said chamber with a gas;
(e) applying positive pressure pulses to said gas within said chamber; and
(f) applying localized pressure on said body to an artery extending in said part to inhibit arterial flow from said part toward the heart during said positive pulses.

9. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:
(a) enclosing a part of a body to be treated in a chamber;
(b) said chamber conforming to the shape of said part therein and the interior surfaces of said chamber being in juxtaposition with corresponding surfaces of said part;
(c) sealing said part in said chamber without substantially affecting the circulation in said part;
(d) filling said chamber with a gas;
(e) applying alternate negative and positive pressure pulses to said part by applying said pulses to said gas;
(f) applying localized pressure during said positive pulses on said body to an artery extending in said part to inhibit arterial flow from said part toward the heart; and
(g) applying localized pressure to a vein extending in said part during said negative pulses.

10. The combination of a variable liquid pressure device for affecting circulation in a part of the body of a human being or an animal, and means for controlling pulsating flow of blood in said part, comprising:
(a) a chamber for containing a liquid under pressure,
(b) said chamber having an opening adapted to receive a part of a body;
(c) a seal being formable at said opening in contact with said body to close said chamber, said seal applying a pressure low enough to said part so as to not substantially affect the circulation in said part;
(d) means to fill said chamber with liquid after said opening is closed;
(e) means to apply positive pressure pulses to all of said liquid; and
(f) means adapted to provide a localized pressure on an artery extending in said part to occlude arterial flow from said part toward the heart during the period of said pulses.

11. The combination of a variable liquid pressure device for affecting circulation in a part of the body of a human being or an animal, and means for controlling pulsating flow of blood in said part, comprising:
(a) a chamber for containing a liquid under pressure,
(b) said chamber having an opening adapted to receive a part of a body;
(c) a seal being formable at said opening in contact with said body to close said chamber, said seal applying a pressure low enough to said part so as to not substantially affect the circulation in said part;
(d) means to fill said chamber with liquid after said opening is closed;
(e) means to apply alternate positive and negative pressure pulses to all of said liquid;
(f) means adapted to provide a localized pressure on an artery extending in said part to inhibit arterial

flow from said part toward the heart during the period of said positive pulses; and

(g) means adapted to provide a localized pressure to a vein extending in said part during the period of said negative pulses to assist the action of the vein check valves.

12. The combination of a variable gas pressure device for affecting circulation in a part of the body of a human being or an animal, and means for controlling pulsatory flow of blood in said part, comprising:

(a) a chamber for containing a gas under pressure and having an opening to receive a part of a body,

(b) said chamber being adapted to conform to the shape of said part and the interior surfaces of said chamber being adapted to be in juxtaposition with corresponding surfaces of said part;

(c) a seal being formable at said opening in contact with said body to close said chamber, said seal applying a pressure low enough to said part so as to not substantially affect the circulation in said part;

(d) means to fill said chamber with gas after said opening is closed;

(e) means to apply positive pressure pulses to said gas in said chamber; and

(f) means adapted to provide a localized pressure on an artery extending in said part to inhibit arterial flow from said part toward the heart during the period of said positive pulses.

13. The invention according to claim **12** including:

(a) means to apply negative pressure pulses to said gas alternately with said positive pressure pulses; and

(b) means adapted to provide a localized pressure to a vein extending in said part during the period of said negative pulses to assist the action of the vein check valves.

14. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:

(a) applying a positive pressure pulse to a part of a body to improve the normal direction flow in an artery, the capillaries, and the veins in said part; and

(b) occluding said artery to said part at a point upstream of a portion of said part to close the artery and to prevent reverse flow toward the heart in said artery during said pressure pulse, and without restricting the normal direction flow toward the heart of the blood in the part downstream of said point.

15. A method of improving the blood circulation in a part of the body of a human being or an animal, comprising:

(a) enclosing a part of a body to be treated in a chamber;

(b) sealing said part in said chamber;

(c) filling said sealed chamber with liquid;

(d) varying the pressure of all of said liquid alternately positively and negatively a predetermined amount at a predetermined rate; and

(e) occluding an artery to said part at a point upstream of a portion of said part to be affected by said varied pressures to close said artery and to prevent reverse flow toward the heart in said artery during the periods the varied pressures applied are positive, and without restricting the normal direction flow toward the heart of the blood in the part downstream of said point.

16. A method of improving the blood circulation in a part of a body of a human being or an animal, comprising:

(a) enclosing a part of a body to be treated in a chamber;

(b) said chamber conforming to the shape of said part therein and the interior surfaces of said chamber being in juxtaposition with corresponding surfaces of said part to provide a minimum of space between said surfaces;

(c) sealing said part in said chamber;

(d) filling said chamber with a gas;

(e) applying positive pressure pulses to said gas within said chamber; and

(f) occluding an artery to said part at a point upstream of a portion of said part to be affected by said pressure pulses to close said artery and to prevent reverse flow toward the heart in said artery during the periods of said positive pressure pulses and without restricting the normal direction flow toward the heart of the blood in the part downstream of said point.

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RICHARD A. GAUDET, *Primary Examiner.*

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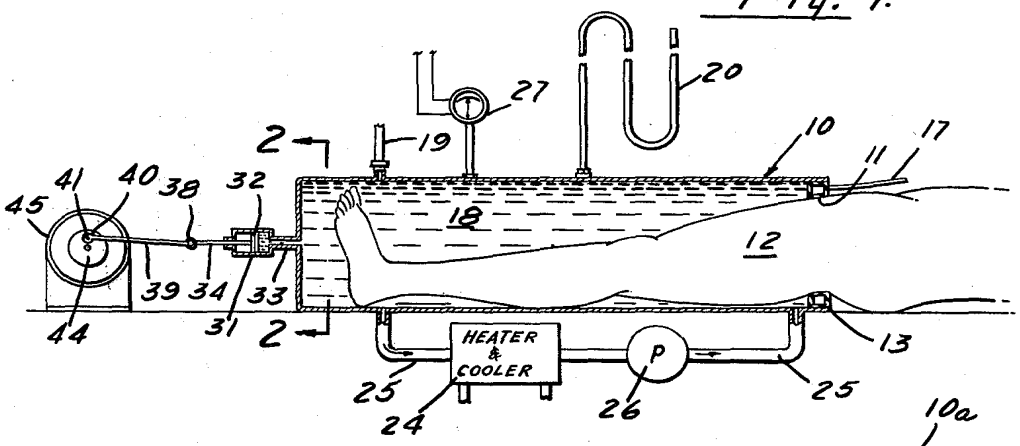
June 25, 1963 N. A. MacLEOD 3,094,983

BLOOD CIRCULATION DEVICE AND METHOD

Filed July 25, 1961 3 Sheets-Sheet 1

Fig. 1.



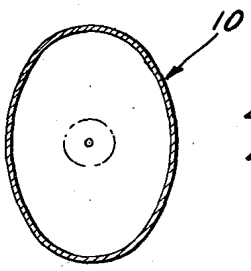


Fig. 2.

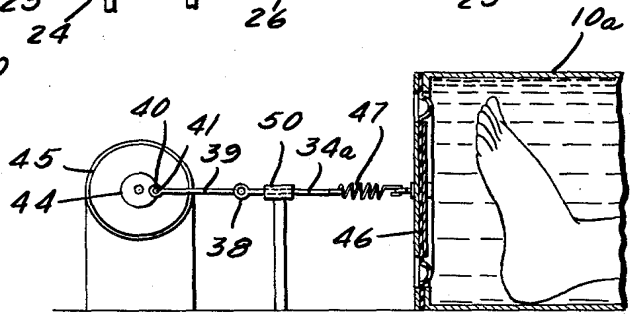


Fig. 3.

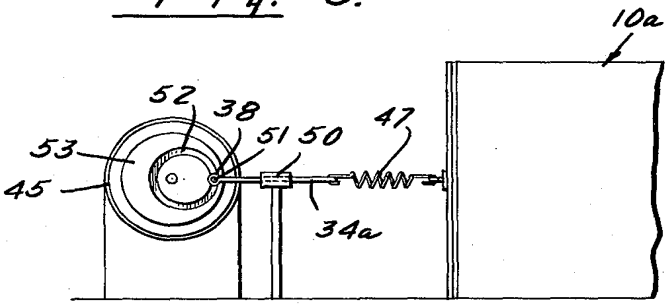


Fig. 4.

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June 25, 1963 N. A. MacLEOD 3,094,983

BLOOD CIRCULATION DEVICE AND METHOD

Filed July 25, 1961 3 Sheets-Sheet 2

Fig. 5.

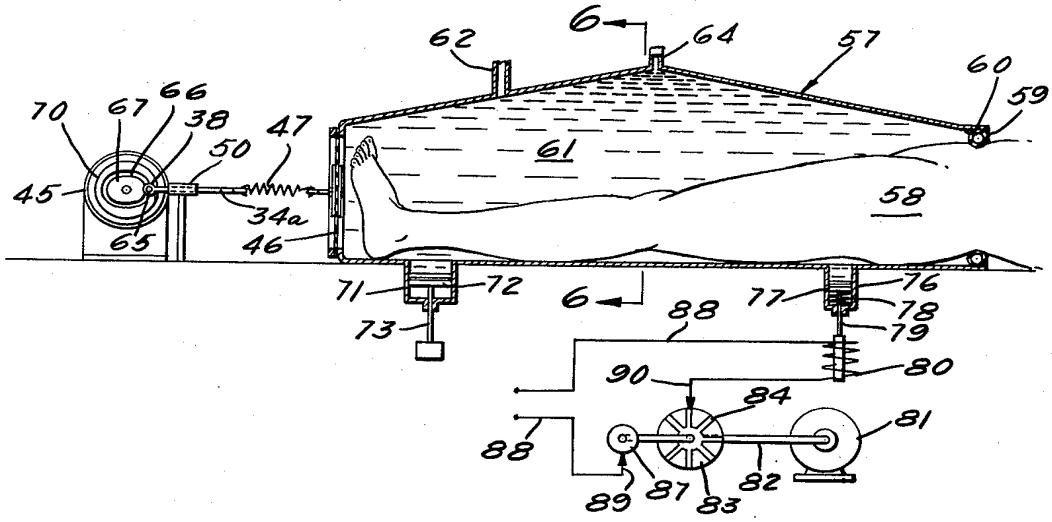


Fig. 6.

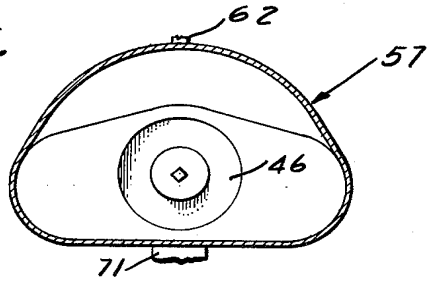


Fig. 7.

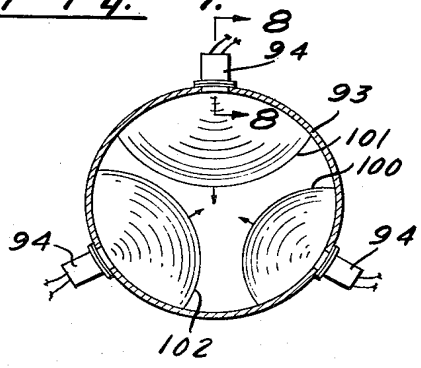
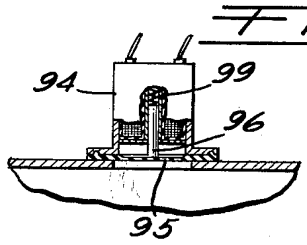


Fig. 8.



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BLOOD CIRCULATION DEVICE AND METHOD

Filed July 25, 1961 3 Sheets-Sheet 3

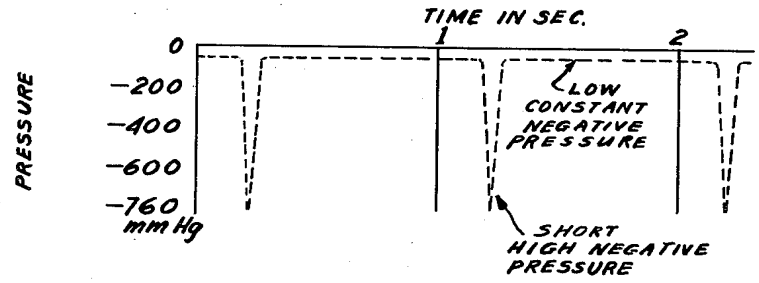

Fig. 9.

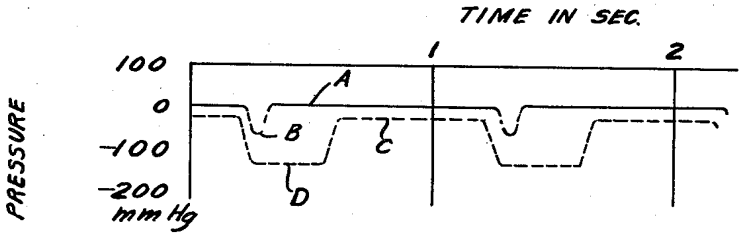

Fig. 10.

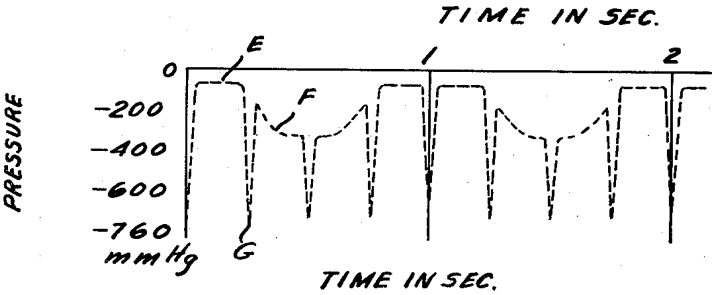

Fig. 11.

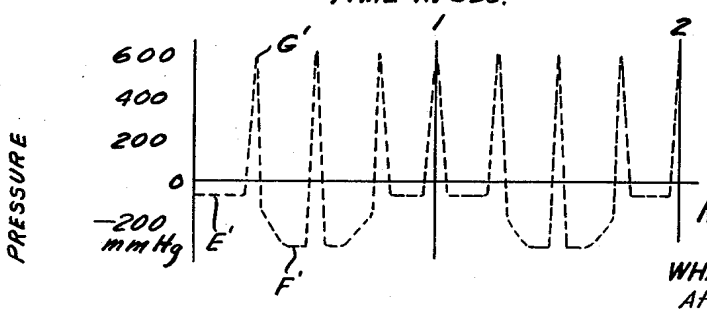

Fig. 12.

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United States Patent ce 3,094,983
Patented June 25, 1963

3,094,983

BLOOD CIRCULATION DEVICE AND METHOD

Norman A. MacLeod, La Habra, Calif., assignor of thirty-six percent to R. Welton Whann and eighteen percent to Wilbur A. Selle, Los Angeles, and ten percent to Frank F. Reed, Pasadena, Calif.

Filed July 25, 1961, Ser. No. 126,586
23 Claims. (Cl. 128—40)

This invention relates generally to a method and apparatus for producing rapid and rhythmic pressure variations within parts of the human body or of animals for the purpose of affecting the metabolism of the parts so treated. Treatment according to the invention provides beneficial and corrective results in the muscular, vascular, nervous, lymphatic and skeletal systems.

In the prior art, it has been attempted to produce pressure variation, particularly in the limbs, by varying the pressure of a gas within a closed chamber. Since such a pressure variation involves the addition or removal of the gas, usually air, the rate of rise or fall of pressure within the chamber has been relatively slow and the consequent pressure variation in the body part has been as slow or slower. For example, to reduce the pressure by one half requires the removal of one half of the gas volume. In addition, the variation of pressure in the gas surrounding the limb has produced corresponding and unavoidable variations in temperature, and these variations are generally undesirable during a particular treatment.

Further, according to the present invention, it has been found desirable that the cycle of pressure variation in the chamber should be similar or related to that of the heart. However, in the prior art, where gas has been used, the rate of cyclic operation has been usually 15 to 50 seconds or more per cycle whereas the heart beat produces internal fluctuations of pressure in the order of one beat per second.

It is also known that while blood will flow comparatively unrestrictedly away from the heart through the main arteries, it is prevented from moving away from the heart through the main veins by a system of check valves. Hence, any reduction in pressure in the distant parts of the human body will tend to increase the flow of blood through the arteries, but will have slight effect upon the veins because of the check valves. Indeed, the presence of these check valves in the veins will cause all externally produced pressure fluctuations on the venous side to be translated into increased rate of flow towards the heart. Further, if pressure reduction in the distant parts of the body is pulsed at a rate corresponding to the delivery of blood to the arteries from the heart, according to the invention, it will help such blood flow significantly.

In adult human beings, for example, variations in pressure in the body, and particularly diminished pressure in the extremities, produce a definite improvement in arterial circulation. This effect has been known for almost 150 years and many attempts have been made to enhance this general improvement. However, all of these have used relatively long cycles of rhythmic pressure variation in the obviously convenient use of a gas, such as air, as the surrounding medium. None have used a complete, substantially gas-free liquid medium or have contemplated very fast fluctuations of the pressure of the order of the heart beat rate or greater, nor have they contemplaed very sudden changes in pressure to an extreme where actual cavitation could occur. In the practice of this invention, very sudden pressure changes sufficient to induce pressure waves in the liquid medium and in the body are used. Further, extremes of pressure drop are proposed to induce momentary and microscopic cavitation, or bubble formation, in the blood, with almost

immediate readsorption, the dwell of this low pressure being relatively short. Such cavitation is favored by the sudden lowering of pressure but in the absence of hydrophobic surfaces, which are generally not present in the human body, gas bubbles will rapidly disappear.

The general effect of my invention is to produce at will intense and rapid pressure vibrations of such controllability in time and point of origin as to create focusing effects, and also of such a generally efficient nature as to stimulate, not only the circulation of the blood, but also the metabolism of the individual organs and cellular tissue.

It will be appreciated that such rapid vibrations will affect the character of tissue and particularly of membranes and cell walls in such a way as to increase the rate of osmosis and other liquid phenomena associated with metabolic processes.

It is an object of the present invention to provide an improved method and apparatus for improving the metabolism of parts of human bodies or animals to produce beneficial and corrective results in the muscular, vascular, nervous, lymphatic and skeletal systems.

It is another object of the invention to provide pressure changes within a body at a rate as great or greater than that resulting from the operation of the normal heart and to provide these changes in pressure in cycles as rapid as those of the average heart beat in normal operation and even in fibrillation.

It is a further object of this invention to produce pressure drops in portions of the body being treated, synchronized with the arrival of the pressure pulse from the heart beat in the arteries in said portions of the body.

It is another object of this invention to impose a cyclic pressure variation corresponding to the normal heart beat when the heart is in fibrillation and so induce the heart to return to normal rhythmical action.

It is still another object of the invention to provide within a body not only a rate of pressure rise or fall greater than accomplished by pneumatic methods, but also to provide very great pressure differences for very short periods of time.

It is a further object of the invention to provide rapidly changing pressures so as to create positive (high pressure) and negative (rarefaction) pressure waves which can be made to travel through the various parts of the body under treatment.

It is a still further object of the invention to provide within a body being treated, small amplitude shock waves, using positive and negative pressure variations alone or in alternating sequence of positive and negative waves.

It is another object of the invention to create a series of pressure waves at various points in a pressure chamber and at controlled intervals so that a focusing action can be obtained at a depth within a body being treated to profoundly affect a particular zone under treatment.

It is still another object of the invention to maintain a pressure on a part of the body being treated at a constant level, other than atmospheric, and to induce rhythmic pulsations in pressures above or below, or above and below the constant pressure.

It is a further object of the invention to provide in a treating chamber relatively slow rhythmic change in pressure and to superimpose upon the latter sharp, staccato fluctuations in pressure.

It is a still further object of the invention to provide in a liquid pressure chamber vibratory pulsations at rates between 100 and more than 20,000 vibrations per second.

It is another object of the invention to maintain the portion of the body being treated in a liquid pressure chamber under a constant temperature.

It is still another object of the invention to stimulate metabolic processes in the portion of the body being

treated by increasing molecular movement of tissues therein in a predetermined manner.

It is a further object of the invention to provide a treatment chamber having curved inner surfaces which can be used to generate pressure waves at a multiplicity of points so that a deep-seated focus of wave energy will result.

It is a further object of the invention to provide a cycle through a multiplicity of generative pressure pulse points of origin by progressive stimulation of waves at very short (microsecond) intervals so as to cause an aforesaid deep-seated focus to move in any desired manner.

Another object of the invention is to provide an apparatus and method for stimulating and assisting general blood circulation in a manner so as to relieve the heart muscles of their work load. This is especially important in cases of severe illness, when normally the desired increase in circulation is affected by increasing the oxygen intake, a process which stimulates metabolic action at a time that the body is actually functioning to conserve it.

Still another object of the invention is to cause mechanical working of smaller blood vessels, particularly the capillaries, so that the blood flow and therefore local basic metabolism, will be improved. This result is particularly important as a means of combating the reduction in the "tone" of the blood vessels, the deteriorating condition which is progressive with age in the adult human being, and which is due to the progressive reduction of the diameter of blood vessels and the thickening of the walls of the blood vessels that occurs with increasing age.

Further objects and advantages of the invention may be brought out in the following part of the specification wherein small details have been described for the competence of disclosure, without intending to limit the scope of the invention which is set forth in the appended claims.

Referring to the accompanying drawings, which are for illustrative purposes only:

FIG. 1 is a side elevational view, partially in cross section, of an apparatus according to the present invention;

FIG. 2 is a cross sectional view taken as indicated by the line **2**—**2** in FIG. 1;

FIG. 3 is a fragmentary cross sectional view of another embodiment of the invention;

FIG. 4 is a view of an embodiment of the invention, similar to that in FIG. 3, and having another type of actuating means;

FIG. 5 is a side elevational view of still another embodiment of the invention, having a plurality of pressure varying means;

FIG. 6 is a cross sectional view taken as indicated by the line **6**—**6** in FIG. 5;

FIG. 7 is a cross sectional view of a liquid containing chamber, similar to that in FIG. 1, and illustrating pressure waves of different magnitude induced around the periphery of the chamber;

FIG. 8 is a fragmentary cross sectional view taken as indicated by the line **8**—**8** in FIG. 7;

FIG. 9 is a graphical representation of pressures effected by the invention on a body, the pressures being comprised of a low constant negative and a high pulsed negative;

FIG. 10 is a graphical illustration of typical pressure variations for use with a 60-beat per minute heart pulse;

FIG. 11 is a graphical illustration of the use of three variations in pressure—a constant negative pressure; a deep, sharp, short dwell negative pressure; and a slow, medium negative pressure; and

FIG. 12 is a graphical representation of the use of a constant negative pressure interspersed with high, short, positive pressures and relatively slow and easy negative pressures.

Referring now to the drawings, in FIG. 1 there is shown an open-ended, elongated chamber **10**, having an elliptical cross section, as shown in FIG. 2, and being adapted to receive in its open end **11** the substantial portion of a human leg **12**. A seal is formed so as to close the chamber by means of expandable tube **13** attached to the chamber, and which is shown to be inflated so as to be in snug, sealing contast with the periphery of the leg. The tube **13** may be inflated by conventional means through tube **17**.

The chamber **10** is shown to be filled with a liquid **18**, such as water, the latter being supplied to the chamber after the leg is sealed therein through inlet **19**. The chamber must be completely filled with the liquid and as it is filled, the manometer **20** may serve as the vent means to permit all the air in the chamber to be discharged.

In order that the temperature of the liquid **18** may be maintained at the desired constant temperature, a heat exchanger **24** is connected to the chamber by means of a pipe **25** to which is also connected a circulating pump **26**. The pump is run as necessary to circulate the liquid through the heat exchanger. Extending upwardly from the chamber and connected thereto is a piezoelectric gauge which measures very rapid and small pressure changes in the liquid.

At the left end of the chamber in the drawing, is a cylinder **31** having a reciprocating piston **32** therein. One end of the cylinder is connected to the chamber by a tube **33** so that movement of the piston **32** will change the pressure within the chamber. Through the other end of the cylinder extends a piston rod **34**, connected to the piston **32**. The rod **34** has its outer end **38** rotatably secured to a connecting rod **39** having its one end **40** rotatably secured to an eccentric pin **41** secured on a wheel **44** and driven by motor **45**. Thus, the operation of the motor rotates pin **41** so as to reciprocate rods **39** and **34** and the piston **32**. The piston may be adjusted with a starting position either with a zero gauge pressure or a constant positive or negative pressure, and any movement of the piston will then either increase the pressure in chamber **10** or decrease it.

In FIG. 3, there is a chamber **10***a*, similar to chamber **10**, having at its left end in the drawing and sealingly engaged therewith, a flexible diaphragm **46**. Attached to the diaphragm is a spring **47**. At the outer end of the spring is attached a rod **34***a* supported in a bearing **50** and having its outer end **38** secured to be reciprocated by connecting rod **39**, driven by the motor **45**.

Here, if the spring **47** is a tension spring, it can be set to provide a permanent suction on the chamber **10***a*, and which in FIG. 3 can be increased by rotation of the wheel **44** 180 degrees and then again decreased to the low suction. Similarly, if a compression spring is used, a permanent pressure can be exerted in the tank and this can be either increased or decreased, depending upon starting position. If the spring **47** in FIG. 3 were a compression spring, the highest pressure in tank **10***a* would be exerted in the position shown in FIG. 3.

In FIG. 4, the chamber and spring are the same as in FIG. 3. Here, however, the outer end **38** of the rod **34***a* is secured for rotation on a pin **51** which extends into and is loosely fitted in a circular groove **52** in wheel **53** which is adapted to be rotated by the motor **45**. Since groove **52** is eccentric relative to the rotation of wheel **53**, as the latter is rotated the pin **51** will be moved by the rotating groove **52** so that the rod **34***a* and the spring **47** will be reciprocated, the pin having a constant vertical position.

In FIGS. 5 and 6, another embodiment of the invention is illustrated. Here, a chamber **57** is provided to receive both legs and a portion of the body **58** up to approximately the waist line about which the sealed tube **59** is snugly fitted, the seal being secured in the opening **60** of the chamber.

The chamber has a raised, central upper portion terminating in an air bleed-off tube **64**. Thus, as the chamber is filled with a liquid **61** through inlet **62**, the liquid being under pressure, all of the air will be forced out of the highest point of the chamber through the tube **64**.

In FIG 5, three separate pressure variation means are

provided. On the left end of the tube is a flexible diaphragm **46**, as illustrated in FIGS. 3 and 4. In this arrangement, the end of the connecting rod **38** is on a pin **65** extending into a groove **66** which provides a cam following path for the cam **67**, formed by cutting the groove in a wheel **70** which is rotated by the motor **45**. In the position shown in FIG. 5, any rotation of the wheel **70** will cause the diaphragm to move to the left and thus exert a suction on the chamber so as to reduce the pressure therein. As can be seen from the shape of the cam **67**, the movement of the diaphragm will be slight but relatively rapid.

Extending from the lower end of the chamber **57** adjacent the diaphragm is a cylinder **71** having therein an adjustably-fixed piston **72**. The piston is fixed in position for any particular operation, either to exert a constant negative or a constant positive pressure within the chamber and on the body being treated. The adjustment of the piston may be made, for example, by the rotational adjustment of a rod **73** threadedly engaged in the cylinder and connected to the piston.

Adjacent the open end of the chamber **57** is a second cylinder **76** having therein a reciprocating piston **77**. The piston **77** is held in a normally up position by means of a spring **78**, as shown, if it is to exert an increasing negative pressure, or if it is to exert a positive pressure, it is held downwardly by a spring. Here, a piston rod **79** forms a core of a solenoid coil **80**.

The solenoid **80** is actuated by an electromechanical means comprised of a motor **81** and its shaft **82**, which drives a rotary switch **83** having a plurality of contacts **84**. Also secured to the shaft **82** is a continuous electrical contact roller **87** which forms part of the solenoid circuit **88**, connected to a solenoid operating power supply. Thus, as the motor drives the rotary switch, continuous contact is made by lead **89** with the roller **87**, the latter being connected to contacts **84**, and the solenoid is operated as the circuit is closed when any one of the contacts **84** moves into alignment with lead **90**.

The operation of the solenoid causes the piston **77** to move downwardly and to exert a sharp, negative pressure within the chamber **65** and on the part of the body being treated. As can be seen from the switch **83**, the period of the negative pressure increase is very short but it occurs at a high frequency.

In FIGS. 9–12, the effects of the operation of the pistons or diaphragms in the foregoing embodiments are shown graphically. For example, if the piston **32** in FIG. 1 or the diaphragms **46** in FIGS. 3 and 4 had a presetting of a low constant negative pressure, this pressure would be indicated in FIG. 9 in the low constant negative pressure line. Then, when the piston or diaphragm was moved outwardly away from the chamber at a rapid rate for a fraction of a second, once a second, a high negative pressure, as indicated in FIG. 9, would be produced for a very short period of time, the maximum being reached when the piston or diaphragm had been moved its greatest amount. It should be noted that the slight movement of a very small piston can produce a very large variation in pressure when the chamber is susbtantially entirely filled with liquid.

As previously described, the structure in FIG. 5 may vary the pressure in three different ways at three different amounts for three different periods. One method of operation of this structure is shown in FIG. 10 where the diaphragm **46** is indicated to be at a normal zero pressure, as indicated by the line A, and when actuated creates the rather gradual dip having its nadir at B. A constant negative pressure can be applied by the piston **72** and a slow drop in pressure, as indicated by the line D, can be applied by the piston **77**, the length of the low pressure being determined by the relatively slow rate of the movement of the rotary switch **83** in FIG. 5.

The pressure variations in the graph shown in FIG. 11 can also be accomplished by the structure shown in FIG. 5 where a constant pressure, indicated by the line E, can be applied by the piston **72**. Then, by having a rapid switch **83**, with a fast pulling solenoid coil **80**, the high negative pressure G can be applied at frequent intervals during a second. The third pressure variation can be applied by the actuation of diaphragm **46**, such actuation as indicated by the shape of the graph being relatively slow.

The pressure variation shown in the graph in FIG. 12 could also be accomplished by the structure shown in FIG. 5 with some modification. Here, the line E′ represents the negative pressure applied by the piston **72**; the line F′ indicates the negative pressure applied by the operation of the diaphragm **46**; and the high positive pressure could be applied by the piston **77** with a constantly energized solenoid **80** having the spring **78** to push the piston up and increase the pressure when the solenoid was deenergized. Another way of accomplishing the same result would be by having a constant negative pressure E′ applied by the spring **47** on the diaphragm **46** and by varying operation of the diaphragm by the actuation of rod **34***a* so as to create the pressure indicated by line F′, and then operating the piston **72** at a very rapid rate for a short period to produce the pressure indicated by the line G′. In such an installation, the piston **77** would not be necessary.

In FIGS. 7 and 8, another embodiment of the invention is illustrated. Here, the chamber **93** is cylindrical and is shown only in cross section. Mounted on the chamber and generally evenly spaced with respect to its circumference are three solenoids **94**. Inwardly of each solenoid is a diaphragm **95**, as best seen in FIG. 8. Each solenoid has a core **96** adapted to be moved radially inwardly by a spring **99** when the solenoid is deenergized.

In operation, the solenoids are successively operated so as to induce pressure waves of various amounts, as indicated in FIG. 7, by **100**, **101** and **102**. Such a series of pressure waves at the various points and at controlled intervals creates a focusing action at a depth within the body to affect the particular zone profoundly.

It will be appreciated that while the drawings show the treatment of a leg and lower body, other parts of the body can be so treated. For instance, an arm can be so treated. In fact, by providing a suitable breathing mask and ear plugs to avoid damage to the ear drums, the entire body can be treated. In particular, the advantage of stimulating blood flow in the cranial blood vessels is obvious in cases where reduction in flow can cause impairment of mental functions and in the case of elderly patients, can produce a condition of senility.

It will be further appreciated that the operation of the device in a room at atmospheric pressure will limit the reduction of pressure to a minimum of one atmosphere, whereas if the device and the patient are totally enclosed in an air-filled pressurized chamber where the pressure is maintained at, for instance, from one pound per square inch to fifty pounds per square inch in excess of atmospheric pressure, then the limit of reduction of pressure applied by the device to the patent can be increased to a maximum represented by the sum of the current atmospheric pressure and the over-pressure of the chamber.

Conversely, it is obvious that if the pressure in such chamber is reduced below that of the atmosphere, e.g. to only seven pounds per square inch, then the limit of extra negative pressure which the machine can apply to the part of the body being treated is the pressure in the said chamber.

Again, it will be appreciated that the control of pressure variations of the device can be associated with the heat beat of the patient by the use of a sensing device near the heart which can control the application of pressure variation to the part of the body being treated. Such a sensing device could be a small microphone pick-up which would operate the controls with a suitable delay,

measured in milliseconds, to produce a negative pressure at the part of the body being treated, such negative pressure coinciding with or slightly anticipating or lagging the arrival of the positive pressure pulse from the heart in the arteries at that location.

I claim:

1. In a variable, liquid pressure device for affecting the metabolism of parts of the body of human beings or animals, a chamber for containing a liquid under pressure; said chamber having an opening adapted to receive a part of a body; a seal being formable at said opening in contact with said body to close said chamber; means to fill said chamber with liquid after said opening is closed; and means to vary the pressure of all the liquid in the chamber.

2. In a variable, liquid pressure device for affecting the metabolism of parts of the body of human beings or animals, a chamber for containing a liquid under pressure; said chamber having an opening adapted to receive a part of a body; a seal being formable at said opening in contact with said body to close said chamber; means to fill said chamber with liquid after said opening is closed; and means to vary the pressure of all the liquid in the chamber and to vary the pressure of liquids in the part of the body.

3. In a variable, liquid pressure device for affecting the metabolism of parts of the body of human beings or animals, a chamber for containing a liquid under pressure; said chamber having an opening adapted to receive a part of a body; a seal being formable at said opening in contact with said body to close said chamber; means to fill said chamber with liquid after said opening is closed; means to vary the pressure of all the liquid in the chamber; and means in communication with said chamber to maintain the liquid therein at a predetermined temperature.

4. In a variable, liquid pressure device for affecting the metabolism of parts of the body of human beings or animals, a chamber for containing a liquid under pressure; said chamber having an opening adapted to receive a part of a body; a seal being formable at said opening in contact with said body to close said chamber; means to fill said chamber with liquid after said opening is closed; and means to provide variable pressure changes of all the liquid in said chamber and at various rates.

5. In a variable, liquid pressure device for affecting the metabolism of parts of the body of human beings or animals, a chamber for containing a liquid under pressure; said chamber having an opening adapted to receive a part of a body; a seal being formable at said opening in contact with said body to close said chamber; means to fill said chamber with liquid after said opening is closed; and means to vary the pressure of a constant volume of liquid in communication with said chamber.

6. In a variable, liquid pressure device for affecting the metabolism of parts of the body of human beings or animals, a chamber for containing a liquid under pressure; said chamber having an opening adapted to receive a part of a body; a seal being formable at said opening in contact with said body to close said chamber; means to fill said chamber with liquid after said opening is closed, said seal including a tube defining said opening, said tube being expandable to be snugly fitted around said body part; and means to vary the pressure of all the liquid in the chamber.

7. In a variable, liquid pressure device for affecting the metabolism of parts of the body of human beings or animals, a chamber for containing a liquid under pressure; said chamber having an opening adapted to receive a part of a body; a seal being formable at said opening in contact with said body to close said chamber; means to fill said chamber with liquid after said opening is closed; means to vary the pressure of all the liquid in the chamber, said means including a cylinder in communication with said chamber; a piston in said chamber; and power means to reciprocate said piston in said cylinder.

8. In a variable, liquid pressure device for affecting the metabolism of parts of the body of human beings or animals, a chamber for containing a liquid under pressure; said chamber having an opening adapted to receive a part of a body; a seal being formable at said opening in contact with said body to close said chamber; means to fill said chamber with liquid after said opening is closed; and means to vary the pressure of all the liquid in the chamber, said means including a flexible member forming a portion of a wall of said chamber and means to move said member toward and away from said chamber.

9. In a variable, liquid pressure device for affecting the metabolism of parts of the body of human beings or animals, a chamber for containing a liquid under pressure; said chamber having an opening adapted to receive a part of a body; a seal being formable at said opening in contact with said body to close said chamber; means to fill said chamber with liquid after said opening is closed; first means to vary the pressure of all the liquid in the chamber a predetermined amount at a predetermined rate; and second means to vary the pressure of all the liquid in the chamber a greater predetermined amount at a greater predetermined rate than said first means.

10. The invention according to claim 9 including means to apply a constant negative pressure on all the liquid in the chamber.

11. In a variable, liquid pressure device for affecting the metabolism of parts of the body of human beings or animals, a chamber for containing a liquid under pressure; said chamber having an opening adapted to receive a part of a body; a seal being formable at said opening in contact with said body to close said chamber; means to fill said chamber with liquid after said opening is closed; and means to vary the pressure of all the liquid in the chamber, said means including a plurality of flexible members, each forming a portion of a wall of said chamber, and operating means to move said members relative to said chamber in a cycle of increasing amounts of movement at successive intervals.

12. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; and varying the pressure of all of said liquid a predetermined amount at a predetermined rate.

13. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; and applying predetermined positive and negative pressures to all of said liquid at predetermined rates.

14. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; and producing small amplitude shock waves in all of the liquid at predetermined rates.

15. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; applying a constant pressure in all of the liquid; and inducing rhythmic pulsations to create different pressures in all of the liquid.

16. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; varying the pressure of all of said liquid a predetermined amount at a predetermined rate; and superimposing on said rate sharp staccato fluctuations in pressure.

17. A method of affecting the metabolism of parts of

the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; and maintaining vibratory pulsations in all of the liquid at rates between 100 and more than 20,000 vibrations per second.

18. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; maintaining the liquid at a substantially constant temperature; and varying the pressure of all of said liquid a predetermined amount at a predetermined rate.

19. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; varying the pressure of all of said liquid a predetermined amount at a predetermined rate; and increasing the molecular movement of tissues in said part of the body.

20. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; and generating pressure waves at a plurality of points in said liquid so that a deep-seated focus of wave energy results.

21. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; generating pressure waves at a plurality of points in said liquid so that a deep-seated focus of wave energy results; and cycling said pressure waves by progressive stimulation at microsecond intervals to cause said focus to move in any desired manner.

22. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing a part of a body to be treated in a chamber; sealing said part in said chamber; filling said sealed chamber with liquid; and varying the pressure of all of said liquid a predetermined amount at a rate at a multiple of the heart beat of the body being treated.

23. A method of affecting the metabolism of parts of the body of human beings or animals comprising: enclosing the entire body in a pressurized air-filled chamber; enclosing a part of said body to be treated in a smaller chamber within said air-filled chamber; sealing said part in said smaller chamber; filling said smaller chamber with liquid; and varying the pressure of all of said liquid a predetermined amount at a predetermined rate.

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United States Patent [19]

Grahn

[11] Patent Number: 5,683,438

[45] Date of Patent: Nov. 4, 1997

[54] **APPARATUS AND METHOD FOR CORE BODY WARMING OF MAMMALS EXPERIENCING HYPOTHERMIA**

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[21] Appl. No.: **402,469**

[22] Filed: **Mar. 10, 1995**

[51] **Int. Cl.**[6] **A61F 7/00**

[52] **U.S. Cl.** **607/104**; 607/114; 607/88; 607/96; 607/100; 126/204

[58] **Field of Search** 607/88–96, 100, 607/104, 107–112, 114; 165/46; 383/90; 126/204; 601/15

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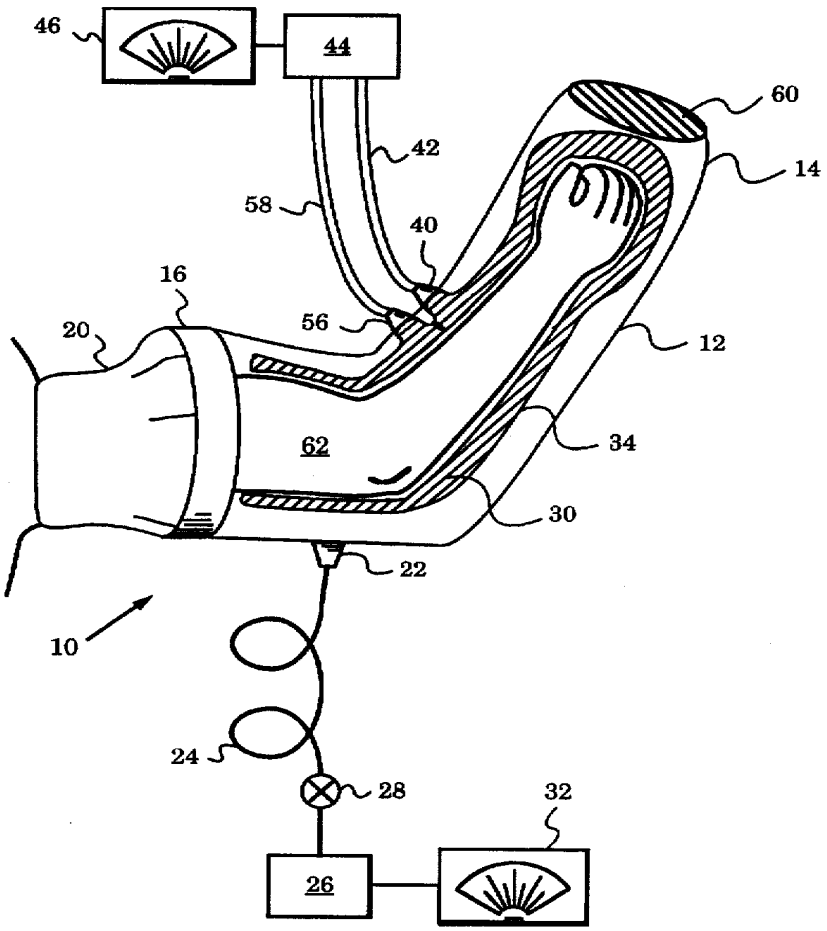
[57] **ABSTRACT**

The invention presents an apparatus and a method for core body warming of hypothermic mammals. The apparatus has an enclosing element to be placed around a predetermined body portion of a mammal in a vacuum-tight manner and a vacuum system connected to the enclosing element for generating and maintaining a predetermined negative pressure, preferably between −20 mmHg and −80 mmHg, inside the enclosing element. A heating unit delivers a thermal energy while the vacuum system is maintaining the predetermined negative pressure. The simultaneous application of thermal energy and negative pressure produces vasodilation which promotes absorption of the thermal energy through the surface of the body portion. The circulatory system of the mammal naturally carries the thermal energy to the core body of the mammal.

20 Claims, 3 Drawing Sheets



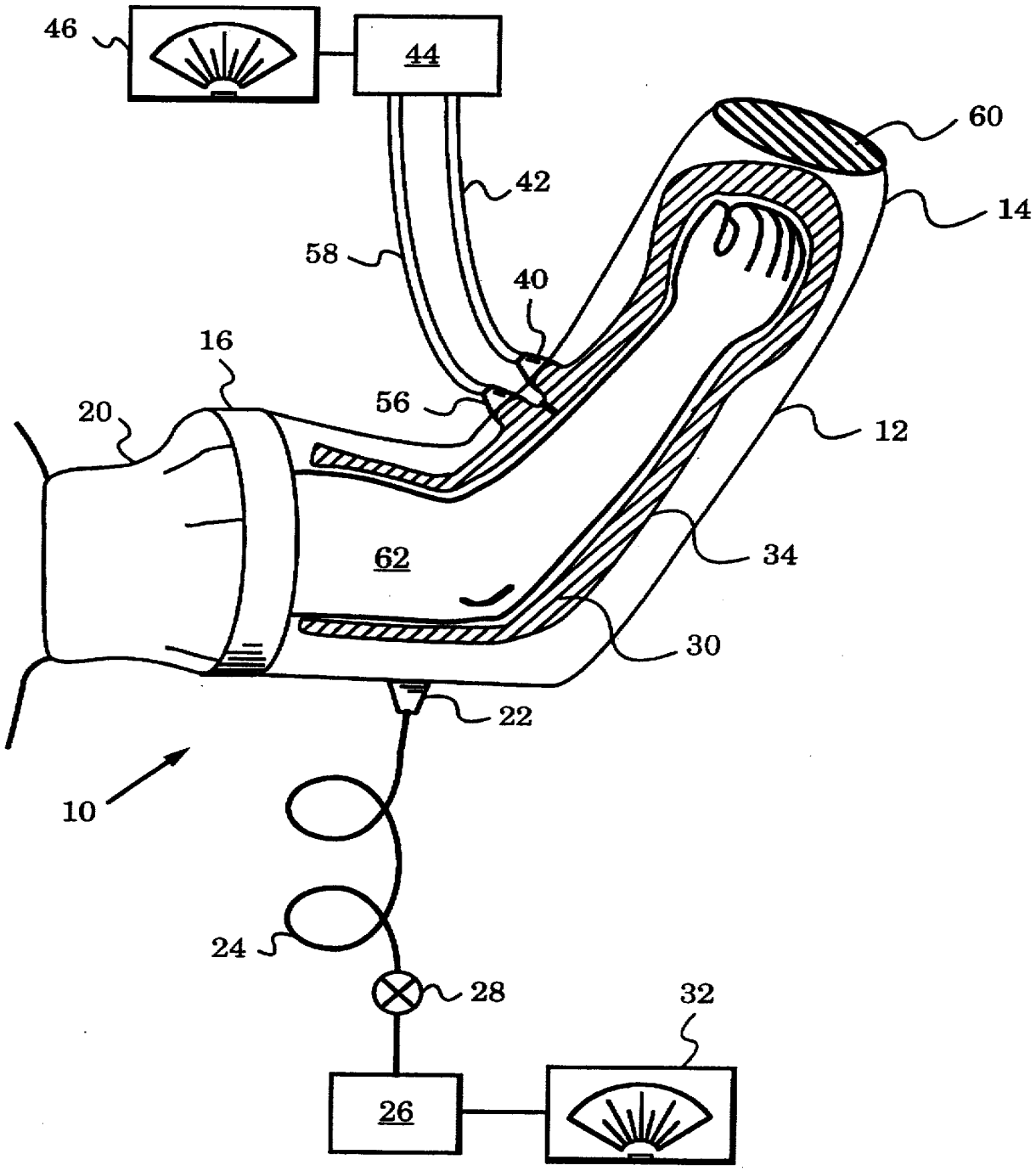


Fig. 1

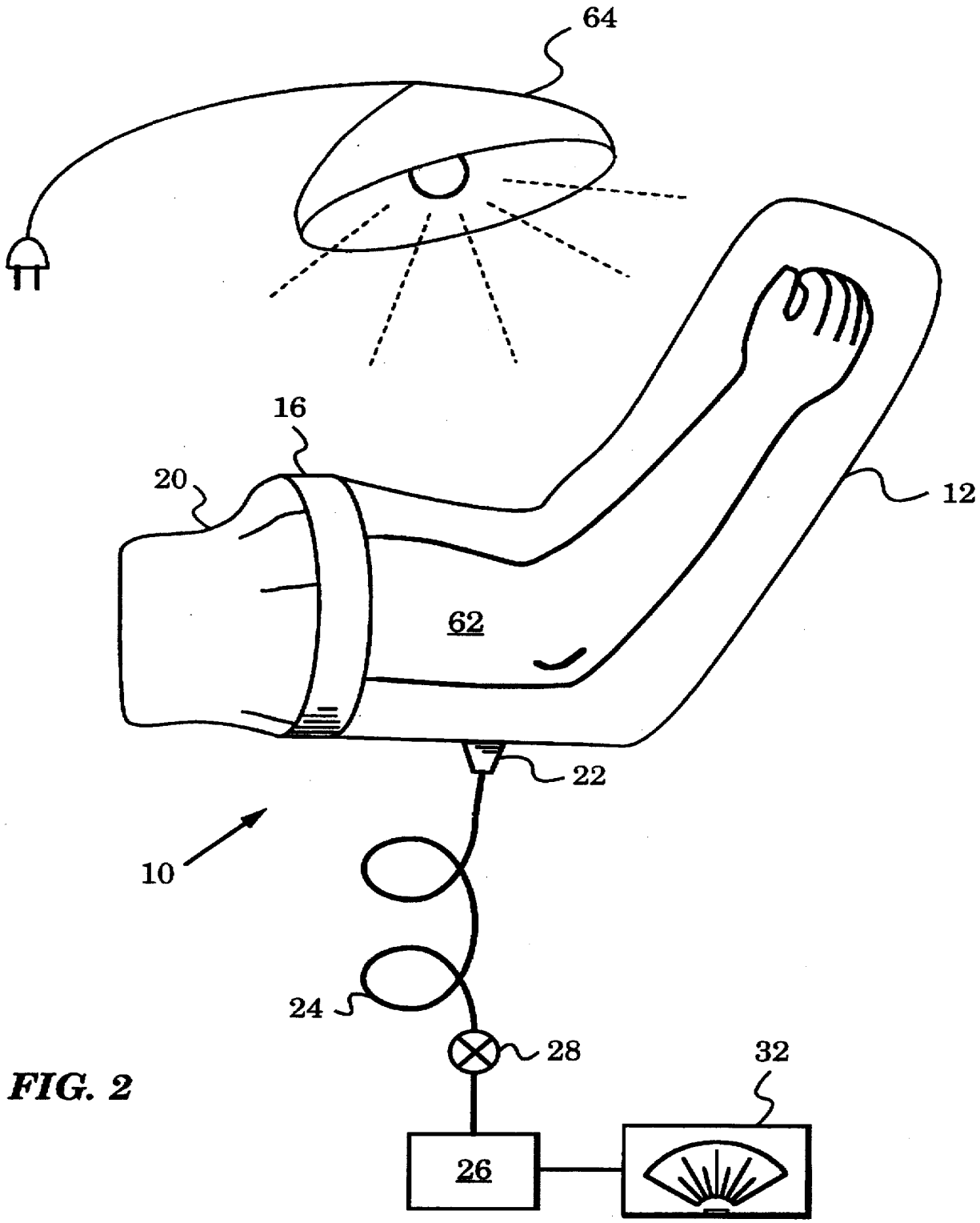


FIG. 2

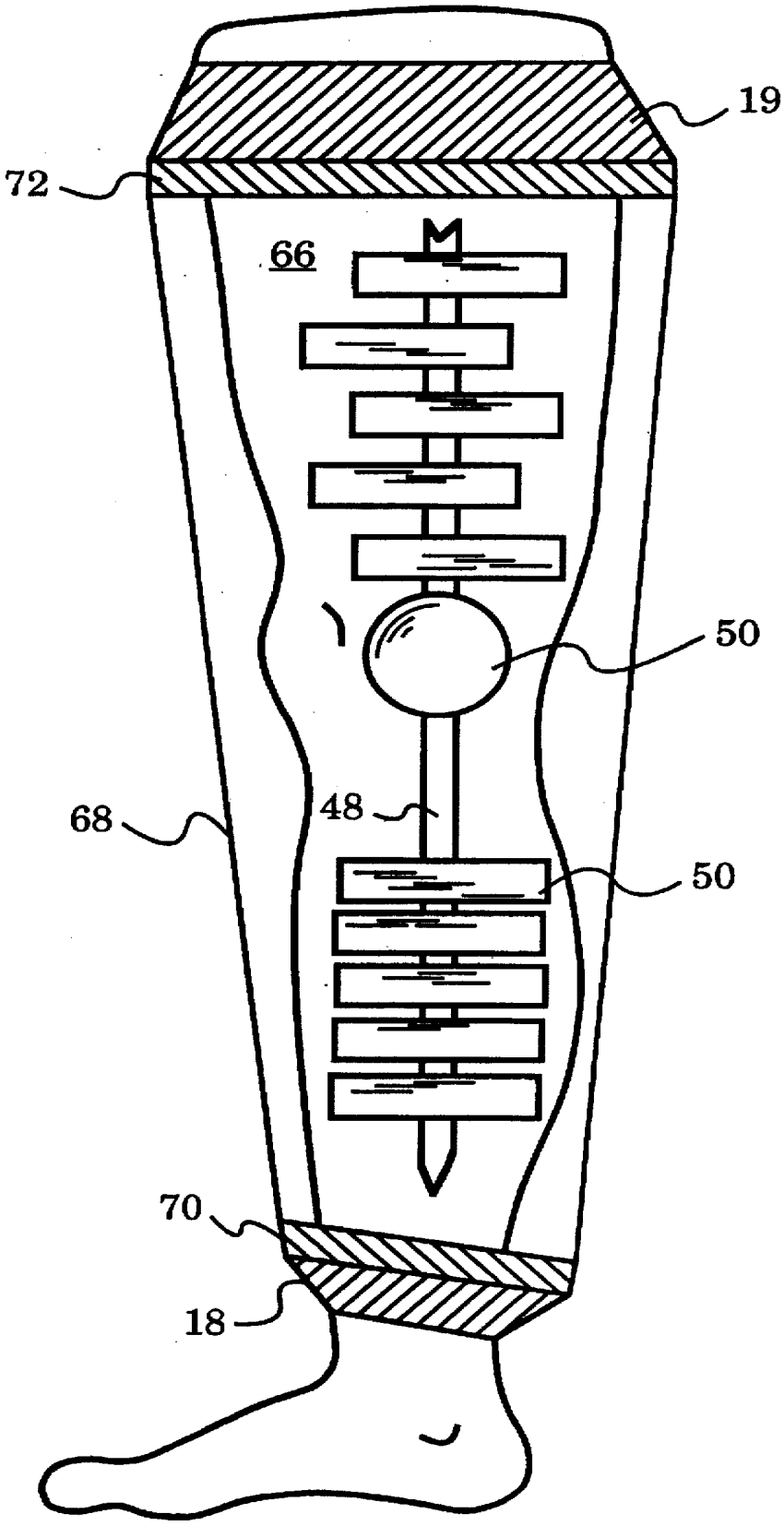


FIG. 3

APPARATUS AND METHOD FOR CORE BODY WARMING OF MAMMALS EXPERIENCING HYPOTHERMIA

BACKGROUND

1. Field of the Invention

The present invention relates to the field of thermal therapeutic applications, and in particular to core body warming in the treatment of hypothermia.

2. Description of Prior Art

Hypothermia results from exposure to conditions where the body cannot generate sufficient heat to compensate for the body heat lost to the environment. Hypothermia impedes normal bodily functions and, if not reversed, can lead to death. Shivering and peripheral vasoconstriction are the body's primary physiologic mechanisms for generating and conserving heat, respectively.

Hypothermia occurs in conditions where the body is exposed to ambient temperatures well below normal physiologic temperature such as immersion in cold water. Hypothermia also results from the administration of general anesthesia. Under general anesthesia, mammals lose the ability to conserve heat by constriction of peripheral blood vessels ("vasoconstriction") or generate heat by shivering ("thermogenesis") in response to cold challenges. As a result, many individuals emerging from general anesthesia experience hypothermia, particularly if the time under general anesthesia is prolonged.

In general, active core rewarming of the body is desired following general anesthesia or other prolonged physiologic exposure to cold. Peritoneal dialysis using warming fluids can be used in cases of severe hypothermia, but this method is invasive and exposes the less severely hypothermic patient to unwarranted risks of morbidity and mortality. Less severe hypothermia can be treated pharmacologically with muscle relaxants, but this intervention decreases shivering which, in turn, impedes physiologic warming and increases the time required to restore normal body temperature. Radiant heat, warm water, or warm air applied to the skin surface alone has only a minimal effect on raising core body temperature because peripheral vasoconstriction impedes heat transfer from the skin to the body core. Breathing warm, humidified air provides some deep body core heating, and there are devices commercially available for that purpose. Inhalation warming methods, however, are relatively slow-acting and may require invasive techniques such as tracheal intubation for effective use.

The challenge has been to develop a means to rapidly, safely, and effectively bring the core body temperature to within normal physiologic range following general anesthesia or other prolonged exposures to cold.

A variety of devices and techniques are known for the therapeutic heating of a part of the body, but these generally are neither designed nor adequate for the transmission of heat to the core of the body. U.S. Pat. No. 4,736,088 describes an electrically driven heating pad and muff structure which directs the flow of heat through a laminate to produce moist heat on a body member.

U.S. Pat. No. 4,747,409 describes a sleeve that contains electric resistance heating elements designed to fit over a body extremity for the purpose of dilating blood vessels; and U.S. Pat. No. 5,074,285 is a device that encloses a human extremity and applies static heat to that extremity simultaneously with a gradient pressure applied repeatedly in timed sequence from a distal to proximal portion of an extremity.

Both of these devices will be ineffective for the treatment of hypothermia because heat applied to the surface of the skin in this manner will not allow the heat to penetrate into the body core.

Another prior-art device for core body warming uses radio frequency waves. U.S. Pat. No. 4,685,462 describes an apparatus that employs mutually inductive first and second helical coils positioned around the torso of a body to produce radio frequency waves that directly rewarm the core body. This device does not have the flexibility to fit around an appendage and may interfere with surgical intervention of the chest and abdomen. In addition, this device may cause disruptive electromagnetic interference in the operating theater or recovery room following general anesthesia.

OBJECTS AND ADVANTAGES OF THE INVENTION

With the foregoing in mind, it is a principal object of this invention to provide a safe, non-invasive apparatus and method for effectively rewarming the core body of patients who have undergone general anesthesia or otherwise have developed hypothermia.

It is another object of this invention to provide a practical core body warming device which will provide heating substantially throughout a central body region containing the heart, can be used safely both in a hospital environment and, in its most portable form, can be easily attached to a hypothermic victim and be safely used as first-aid in a rescue operation.

It is another object of this invention to provide a core body heating apparatus wherein the apparatus is automatically adaptable to subjects of different size and mass.

These and other objects and advantages will become more apparent after consideration of the ensuing description and the accompanying drawings.

SUMMARY OF THE INVENTION

It has been found that by placing a body part such as an arm or a leg in a negative pressure environment, it is possible to vasodilate the capillary beds in that body part. Once the capillary beds have been vasodilated, thermal energy supplied to the skin of that body part is efficiently transduced directly to the core body. Since the remainder of the peripheral vasculature remains vasoconstricted, the distribution of the heat applied to the vasodilated skin regions will be confined to the core body.

In particular, the invention presents a core body warming apparatus having an enclosing element, preferably a pliant sleeve or tube, which is placed around a predetermined body portion of a mammal. Seals establish a vacuum-tight fit between the sleeve and the body portion. The apparatus further includes a vacuum system connected to the sleeve for generating and maintaining a predetermined negative pressure, preferably between −20 mmHg and −80 mmHg, inside the sleeve. A heating unit, preferably a heating blanket or a set of chemical heating elements, is placed inside the sleeve for delivering a thermal energy to the surface of the body portion. A radiant heat source placed outside the sleeve can also be used to deliver the thermal energy. Simultaneously with the delivery of thermal energy the vacuum system maintains the predetermined negative pressure. This produces the local vasodilation which promotes absorption of the thermal energy through the surface of the body portion. The circulatory system of the mammal naturally carries the thermal energy to the core body of the mammal.

The invention further discloses a method for core body warming of mammals experiencing hypothermia. The method calls for application of the negative pressure ranging between −20 mmHg and −80 mmHg and simultaneous delivery of thermal energy to the body surface or skin. Furthermore, the predetermined negative pressure is oscillated for promoting the transport of the thermal energy to the core body of the mammal by its own circulatory system. The particulars relating to both the present apparatus and method are explained in detail in the following description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The presently preferred embodiments of the invention are illustrated in the accompanying drawing in which:

FIG. **1** is a perspective view of an enclosing structure according to the invention.

FIG. **2** is a perspective view of an alternative embodiment of the present invention.

FIG. **3** is a perspective view of another embodiment of the present invention.

DESCRIPTION

As shown in FIG. **1**, a preferred embodiment of the present invention is a core body warming apparatus **10** with an enclosing element **12** in the form of a hollow, tubular, elongated sleeve. Sleeve **12** is dimensioned to fit around a body portion **62**, preferably an appendage, as described below. In the embodiment illustrated in FIG. **1** appendage **62** is an arm.

Sleeve **12** can be made of virtually any non-hazardous material which retains the requisite shape while the interior of sleeve **12** is maintained at negative pressures. In particular, sleeve **12** has to support negative pressures down to at least −85 mmHg. In a preferred embodiment sleeve **12** is made of pliant and elastic materials which can include supporting or reinforcing members. This type of construction easily accommodates movements of arm **62** and thus provides a hypothermic patient more comfort and freedom. In the present embodiment sleeve **12** is a neoprene-impregnated polyester sheath supported on a spring steel wire helix.

Sleeve **12**, as shown in FIG. **1**, has a distal end or rim **14** and a proximal end or rim **16**. Distal rim **14** is capped by a sealing element **60** capable of creating an airtight seal. In this embodiment element **60** is a plastic plate. However, a cap or other sealing element can be used with equal success. In fact, sleeve **12** may be closed off at distal end **14**.

A flexible flange **20** is attached to proximal rim **16**. Flange **20** is preferably made of a synthetic material impermeable to air. The tubular form of flange **20** ensures that it fits snugly around arm **62** and conforms to the arm's shape. In the present embodiment **20** is made of Neoprene (R).

Elongated sleeve **12** is provided with a pressure inlet **22**. A pressure conduit **24**, e.g., a flexible tube, is connected to inlet **22**. The other end of conduit **24** is connected to a vacuum pump **26**. Vacuum pump **26** is a standard pump capable of generating negative pressures down to −85 mmHg and beyond inside sleeve **12**. The delivery of this negative pressure through conduit **24** can be regulated by any conventional mechanisms. In the embodiment shown, an adjustable valve **28** guarantees maintenance of the desired pressure inside sleeve **12**. Conveniently, a readout gauge **32** is also provided for visual pressure indication.

A heating element **34** is lodged inside elongated sleeve **12**. In the preferred embodiment, heating element **34** is a heating blanket filled with a heating fluid **30**. Because of its high heat capacity and general safety, water is particularly well-suited for heating fluid **30**. Heating blanket **34** extends along the length of sleeve **12** and wraps around arm **62**. In fact, it is desirable that the area of contact between arm **62** and blanket **34** be as large as possible.

Blanket **34** is connected to a fluid inlet **40** and a fluid outlet **56**. A supply conduit **42** and a return conduit **58**, both preferably made of a flexible tubing, are attached at inlet **40** and outlet **56** respectively. At their other ends conduits **42** and **58** are connected to a heating and circulating system **44**. Preferably, system **44** is a fluid heater and a circulating pump (not shown). Suitable heaters and pumps are commercially available and commonly known. In addition, system **44** has a control indicator **46** for indicating the temperature of fluid **30** and its rate of flow.

Core body warming apparatus **10** is simple to use. First, a hypothermic person's arm **62** is placed inside sleeve **12** such that heating blanket **34** envelops arm **62** and remains in contact with it. In this position, flange **20** wraps around the upper portion of arm **62**. To ensure that flange **20** conforms closely to the contour of the upper portion of arm **62** the latter is preferably bare.

With arm **62** properly inserted into sleeve **12**, pump **26** is activated to produce a negative pressure between −20 mmHg and −85 mmHg inside sleeve **12**. Under the influence of negative pressure or suction, flange **20** seals tightly around the upper part of arm **62** to preserve the vacuum inside sleeve **12**. At the same time, heating and circulating system **44** is also activated to warm up and pump heating fluid **30** through heating blanket **34**. In particular, heated fluid **30** is delivered through supply conduit **42** and recirculated through return conduit **58**. Control indicator **46** is used for setting the proper flow rate and temperature of fluid **30**. In a preferred embodiment, the amount of thermal energy delivered to the surface of arm **62** is determined based on the body weight of the patient and his initial body temperature.

In particular, the thermal energy required for initial heat-up is determined by the following equation:

$$E_{req} = \frac{\text{heat absorption + heat loss − metabolic heat production}}{\text{time}} \quad [1]$$

Since metabolic heat production in anesthetized subjects is negligible, equation [1] can be simplified to state:

$$E_{req} = \frac{\text{heat absorption + heat loss}}{\text{time}} \quad [2]$$

Heat absorption is calculated from the below equation:

$$\text{Heat absorption} = \frac{\text{specific heat} \cdot \text{body weight} \cdot \Delta T}{3412\ (\text{Btu/kwh})}, \quad [3]$$

where specific heat is expressed in British thermal units (Btu) and the body weight in pounds. ΔT stands for the temperature difference between the initial and the final or desired body temperature. Heat loss is computed according to the equation:

$$\text{Heat loss} = \text{specific heat loss} \cdot \text{exposed surface area} \cdot \text{time}. \quad [4]$$

Rewriting equation [3] under the assumption that the specific heat of a human being is 0.92 Btu/lb·°F. and substituting equation [4] one obtains:

$$\text{Heat absorption} = 0.00027\ (\text{kwh/lb}\cdot^\circ\text{F.}) \cdot \text{weight} \cdot \Delta T. \quad [5]$$

This means that every 100 pounds of body weight must absorb 0.027 kw of heat per hour to warm up by one degree

Fahrenheit. In practice, some variations in this value will be found between human beings and other mammals.

The heat lost by a patient will depend on the size of the exposed area. Frequently, only the face is uncovered. This offers a surface area of approximately 1 sq.ft. to the escaping heat. Under these conditions, the heat loss is approximately 75 watts per hour. Typically, recovery from anesthesia takes 45 minutes, meaning that it is most desirable to rewarm during the same amount of time. Substituting this data in equation [2] and calculating the thermal energy required for warming up each 100 pounds of body weight, one obtains 316 Watts. This is the actual power needed to rewarm the core body in 45 minutes.

The thermal energy which can be safely delivered to the skin by blanket **34** greatly exceeds the 316 Watts computed above. For example, the preferred embodiment uses water at 43° C. as heating fluid **30** moving at a flow rate of 5 l/min. This enables deliveries of thermal energies greatly exceeding the 316 Watts required to warm up the core body and sufficient to overcome typical system losses.

There are two simultaneous effects on arm **62**. The negative pressure inside sleeve **12** causes local vasodilation of the capillary beds while heating fluid **30** supplies thermal energy to the skin. Vasodilated capillaries are very efficient at absorbing heat. They take up the thermal energy offered by blanket **34** and carry it to the core body. Since the remainder of the peripheral vasculature remains vasoconstricted, the distribution of the heat applied to the vasodilated skin regions will be confined to the body core.

To further aid the body in absorbing the thermal energy delivered, the negative pressure value can be changed. For example, a periodic fluctuation or oscillation between −20 mmHg and −85 mmHg may be introduced. The period can be in rhythm with the patient's heart rate. This oscillation will maximize the heat transfer to the core body.

The above apparatus and method of use are safe, non-invasive, and very efficient in rewarming the core body of patients who have undergone general anesthesia or otherwise have developed hypothermia.

An alternative embodiment of the apparatus of the invention is shown in FIG. **2**. Elements shared in common with the preferred embodiment shown in FIG. **1** are labelled with the same reference numbers. In this embodiment the heating blanket and corresponding heating and circulating system are replaced by a radiant heat lamp **64** positioned above sleeve **12**. The material of sleeve **12** is chosen to transmit the light generated by lamp **64** while satisfying all the requirements listed above. Preferably, lamp **64** emits infrared light.

The embodiment of FIG. **2** operates analogously to that of FIG. **1**. After arm **62** is placed inside sleeve **12** vacuum pump **26** produces a negative pressure inside it and causes flange **20** to seal around arm **62**. Simultaneously, lamp **64** is turned on to deliver radiant heat. The radiant heat passes through sleeve **12** and carries its thermal energy to the skin of arm **62**. Since arm **62** is subjected to negative pressure its capillaries are dilated and thus easily absorb and transfer the thermal energy supplied to the skin. As above, that thermal energy is used by the patient's circulatory system to warm the body core.

FIG. **3** illustrates an embodiment of the invention which is adapted for enclosing a leg **66**. In particular, a sleeve **68** designed to be pulled over leg **66** has a bottom rim **70** and a top rim **72**. Also, sleeve **68** is reinforced, e.g., by an internal helical spiral (not shown), against collapse under negative pressure. Two flanges **18** and **19** are attached to rims **70** and **72** respectively. Flanges **18** and **19** are analogous in all respects to flange **20** of the earlier embodiments.

A support rod **48** is located inside sleeve **68**. A number of conventional chemical heating elements **50** are mounted on rod **48**. The vacuum system connected to sleeve **68** is not shown in FIG. **3**.

The embodiment of FIG. **3** operates analogously to the previous embodiments with the difference that thermal energy is delivered to the skin of leg **66** by chemical heating elements **50**. This method of delivering heat is more practical outside hospitals and controlled environments, e.g., in the wilderness during a search-and-rescue operation.

All three of the above mentioned embodiments can be used for human patients and other mammals. The size and shape of the enclosing element or sleeve will differ according to the body part around which the apparatus is placed.

SUMMARY, RAMIFICATIONS, AND SCOPE

The above embodiments of the present invention are only illustrative in purpose and in no way limit the scope of the invention. Many alterations and improvements can be introduced to the above-described embodiments without going beyond the scope of the invention. It is possible to use the present invention to render a patient hypothermic by withdrawing heat from the patient while sustaining a vacuum. The vasodilation produced by the negative pressure will aid in efficiently dissipating heat and lowering the core body temperature.

Obviously, other embodiments and modifications of the invention will readily come to the mind of one skilled in the art having the benefit of the teachings presented in the foregoing description and drawings. Therefore, the scope of the invention should be determined, not by examples given, but by the appended claims and their legal equivalents.

I claim:

1. A system for treating a mammal experiencing hypothermia, said system comprising:

a) an enclosing means for enclosing a body portion of said mammal;

b) a sealing means mounted on said enclosing means for establishing a vacuum-tight fit between said body portion and said enclosing means;

c) a vacuum system connected to said enclosing means for generating and maintaining a predetermined negative pressure inside said enclosing means, thereby causing vasodilation in said body portion; and

d) a heating means for delivering a thermal energy to the surface of said body portion while said vacuum system is maintaining said predetermined negative pressure, so that the local vasodilation in said body portion promotes absorption and transfer of said thermal energy from the surface of said body portion to the core body of said mammal.

2. The system of claim **1** wherein

said heating means comprises a heating blanket with a heating fluid,

said heating blanket is arranged circumferentially inside said enclosing means, and

said heating blanket is adapted to maintain contact with at least a part of the surface of said body portion.

3. The system of claim **1** wherein

said enclosing means comprises a generally tubular sleeve having a distal rim and a proximal rim,

said sealing means comprises a lower seal mounted on said distal rim and an upper seal mounted on said proximal rim,

said body portion comprises an extremity,

and said sleeve has a diameter substantially larger than said extremity such that at least a part of said extremity fits inside said tubular sleeve.

4. The system of claim 3 wherein said tubular sleeve comprises a pliant material for accommodating movements of said extremity.

5. The system of claim 3 wherein

said heating means comprises a heating blanket with a heating fluid,

said heating blanket is arranged circumferentially inside said enclosing means, and

said heating blanket is adapted to maintain contact with at least a part of said extremity.

6. The system of claim 5 wherein said upper seal comprises a flexible flange adapted to fit snugly around said extremity and to seal the inside of said tubular sleeve under the influence of said negative pressure.

7. The system of claim 6 wherein said lower seal comprises a rigid cap.

8. The system of claim 7 wherein a length of said tubular sleeve substantially equals a length of said extremity.

9. The system of claim 6 wherein said lower seal is a flexible flange adapted to fit snugly around said extremity and to seal the inside of said tubular sleeve under the influence of said negative pressure.

10. The system of claim 1 wherein said enclosing means comprises a pliant material for accommodating movements of said body portion.

11. The system of claim 1 wherein said vacuum system comprises:

a) a vacuum pump; and

b) a connecting line between said vacuum pump and said enclosing means for evacuating said enclosing means down to said predetermined negative pressure, said predetermined negative pressure ranging between −20 mm Hg and −85 mm Hg relative to atmospheric pressure.

12. The system of claim 1 wherein

said heating means is positioned outside said enclosing means,

said thermal energy is a radiant energy form, and

said enclosing means comprises a material transmissive to said radiant energy form.

13. The system of claim 12 wherein said heating means comprises a heat lamp.

14. The system of claim 1 wherein said negative pressure has a value between 0 mm Hg and −85 mm Hg relative to atmospheric pressure.

15. The system of claim 1 wherein said vacuum system comprises oscillating means for oscillating said negative pressure, thereby promoting a transport of said thermal energy to a core body of said mammal by a circulatory system of said mammal.

16. A method for core body warming of a mammal experiencing hypothermia, said method comprising the steps of:

a) enclosing a body portion of said mammal in a vacuum-tight manner, thereby defining an enclosure;

b) generating and maintaining a negative pressure within said enclosure, thereby causing a local vasodilation in said body portion; and

c) delivering a thermal energy to a surface of said body portion while maintaining said negative pressure, so that said local vasodilation promotes absorption and transfer of said thermal energy from said surface to a core body of said mammal.

17. The method of claim 16 comprising the step of delivering said thermal energy from outside of said enclosure.

18. The method of claim 16 comprising the step of delivering said thermal energy from inside said enclosure.

19. The method of claim 16 wherein said negative pressure has a value between 0 mm Hg and −85 mm Hg relative to atmospheric pressure.

20. The method of claim 16 comprising the step of oscillating said negative pressure, thereby promoting a transport of said thermal energy to a core body of said mammal by a circulatory system of said mammal.

* * * * *

United States Patent [19]

Norton et al.

[11] **3,878,839**

[45] **Apr. 22, 1975**

[54] **CARDIAC ASSIST APPARATUS**

[75] Inventors: **Robert L. Norton**, Norfolk, Mass.; **William C. Birtwell**, North Scituate, R.I.

[73] Assignee: **Hemodyne, Inc.**, Norfolk, Mass.

[22] Filed: **Feb. 15, 1973**

[21] Appl. No.: **332,629**

[52] **U.S. Cl.** **128/64**

[51] **Int. Cl.** **A61h 7/00**

[58] **Field of Search** ..... 128/64, 24 R, 297, 299, 128/60, 39, 40

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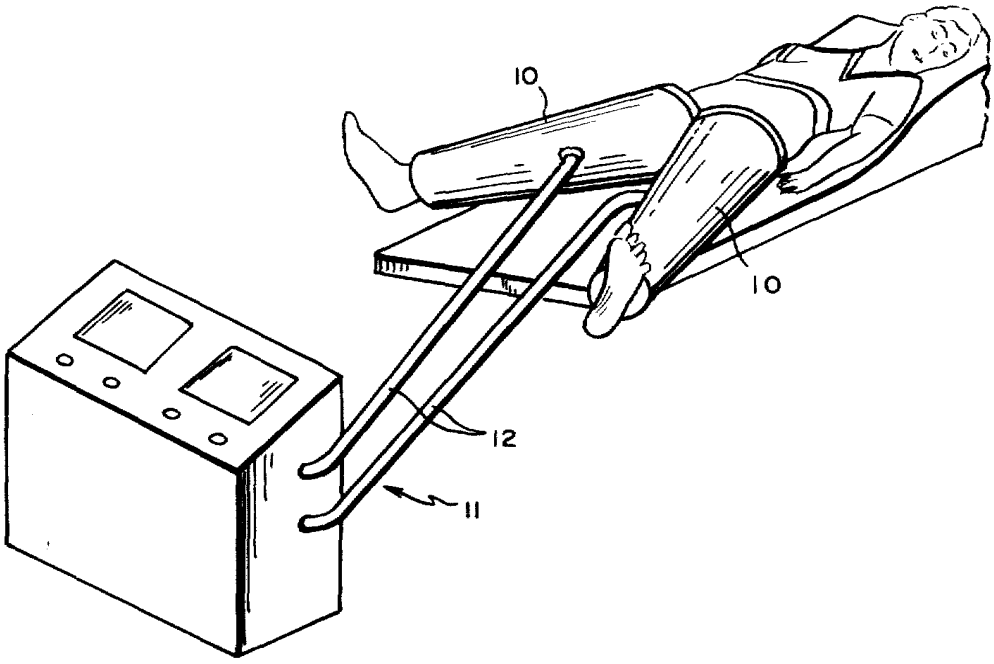
Primary Examiner—Lawrence W. Trapp

Attorney, Agent, or Firm—Dike, Bronstein, Roberts, Cushman & Pfund

[57] **ABSTRACT**

An apparatus for providing external assistance for the circulation of blood in a patient wherein a substantially rigid housing encloses a portion of the patient's body, such as the legs, and a closed pneumatic pressure actuation system is used to actuate a pressure medium, at least a portion of which is gaseous, within the housing to cyclically apply pressure to the body in synchronism with the patient's heartbeat. The housing may be fabricated to provide either a fixed volume or a variable volume therein. Means are provided for effecting an efficient transfer of energy from the actuation system to the pressure medium and thence to the patient's body.

29 Claims, 17 Drawing Figures



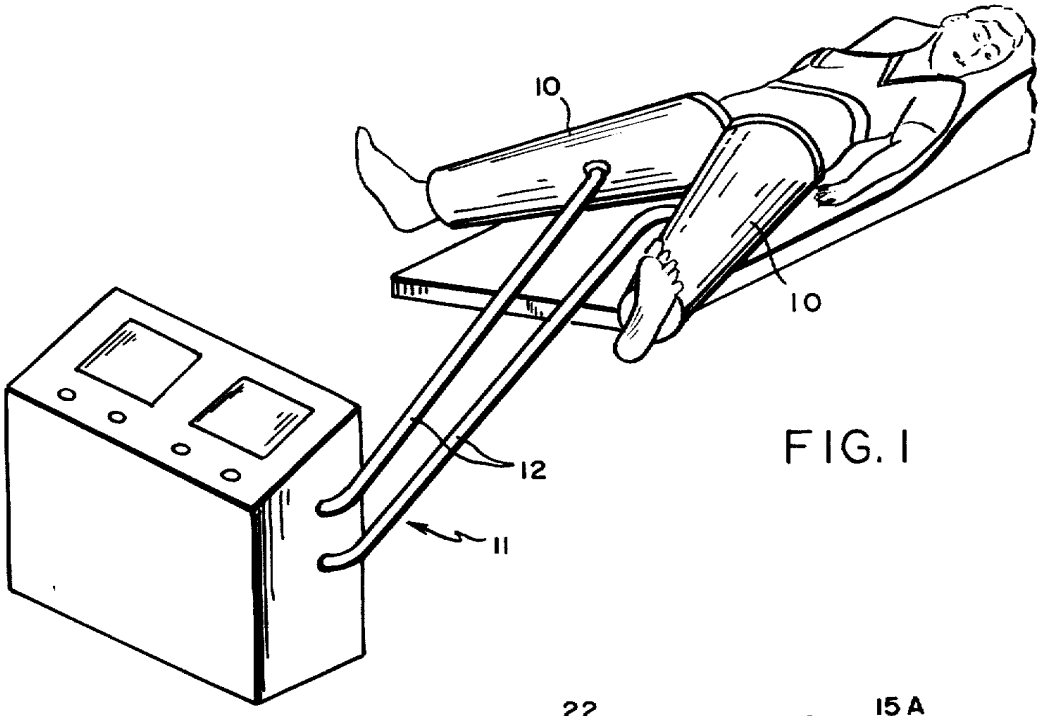


FIG. 1

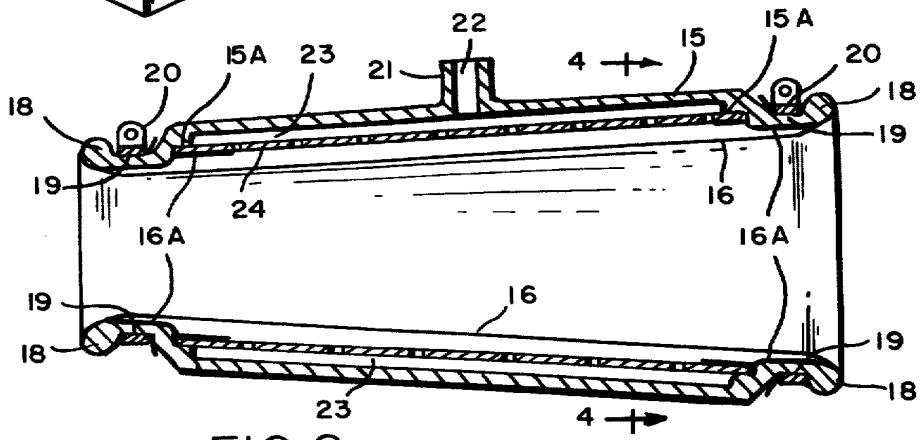


FIG. 2

FIG. 3A

FIG. 3

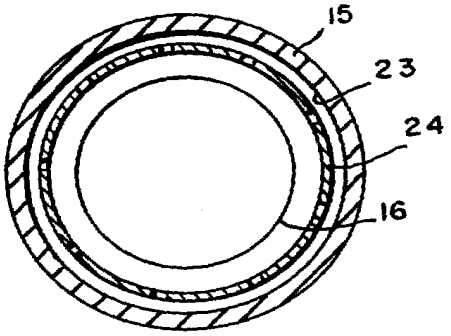


FIG. 4

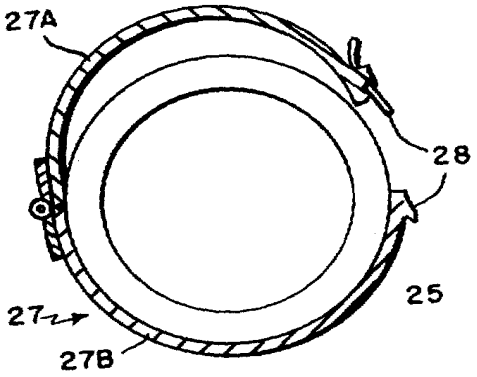


FIG 5

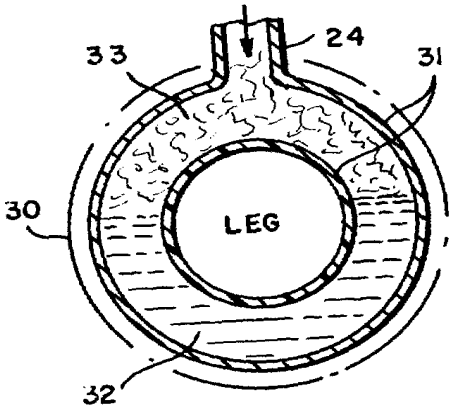


FIG.6

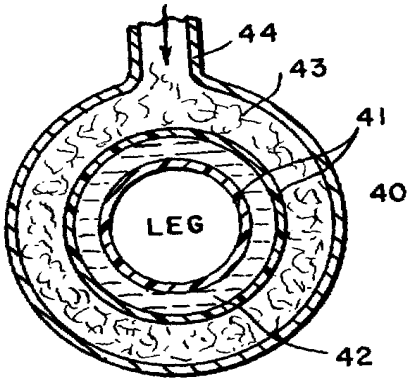


FIG. 7

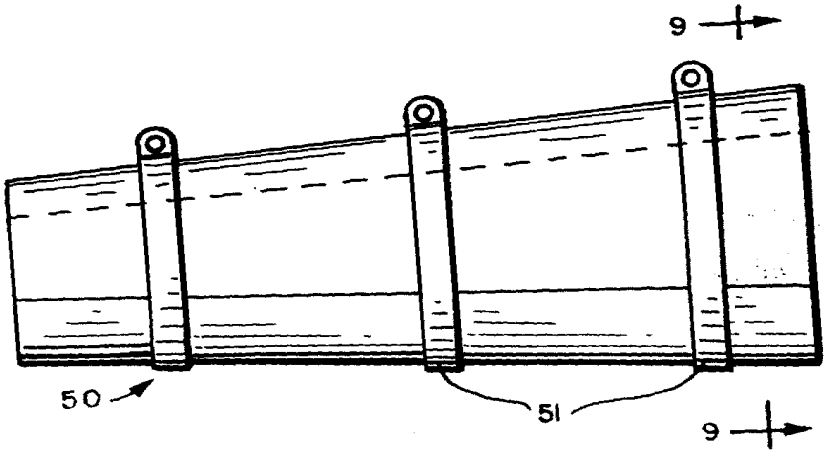


FIG.8

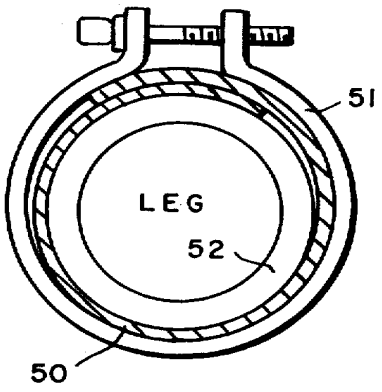


FIG.9

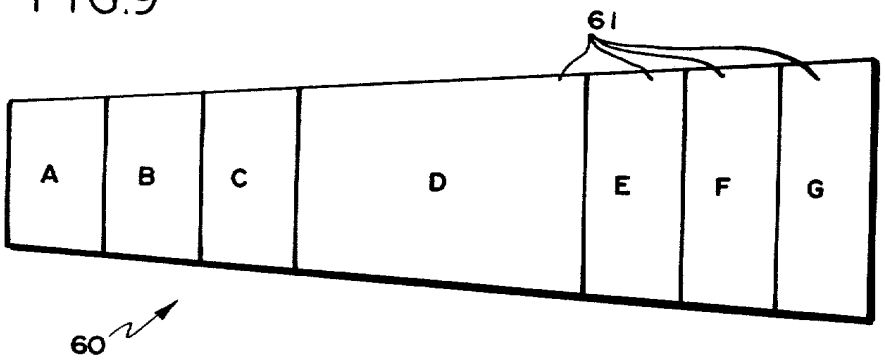


FIG.10

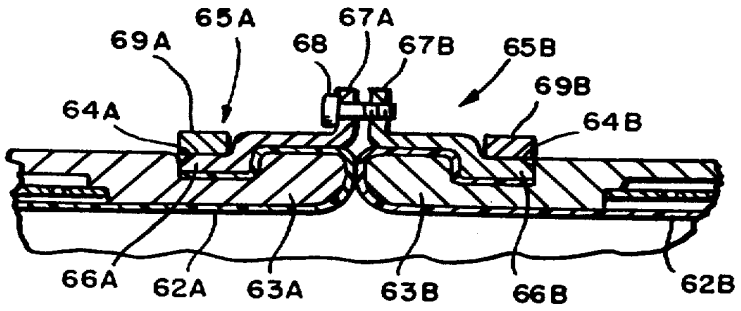


FIG.11

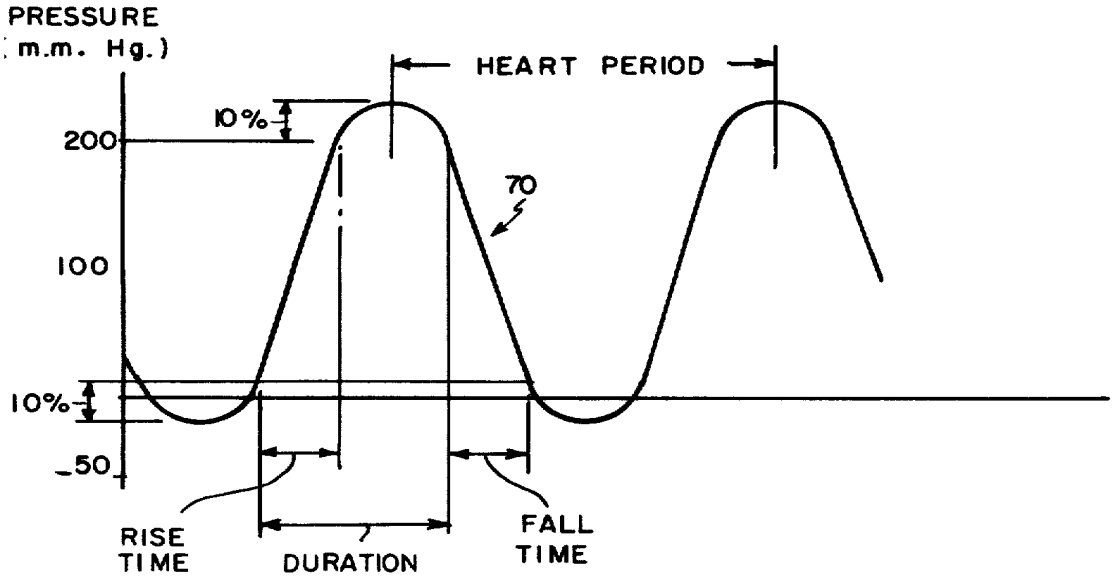

PRESSURE
(m.m. Hg.)
HEART PERIOD
10%
200
70
100
10%
-50
RISE
TIME
DURATION
FALL
TIME

FIG. 12

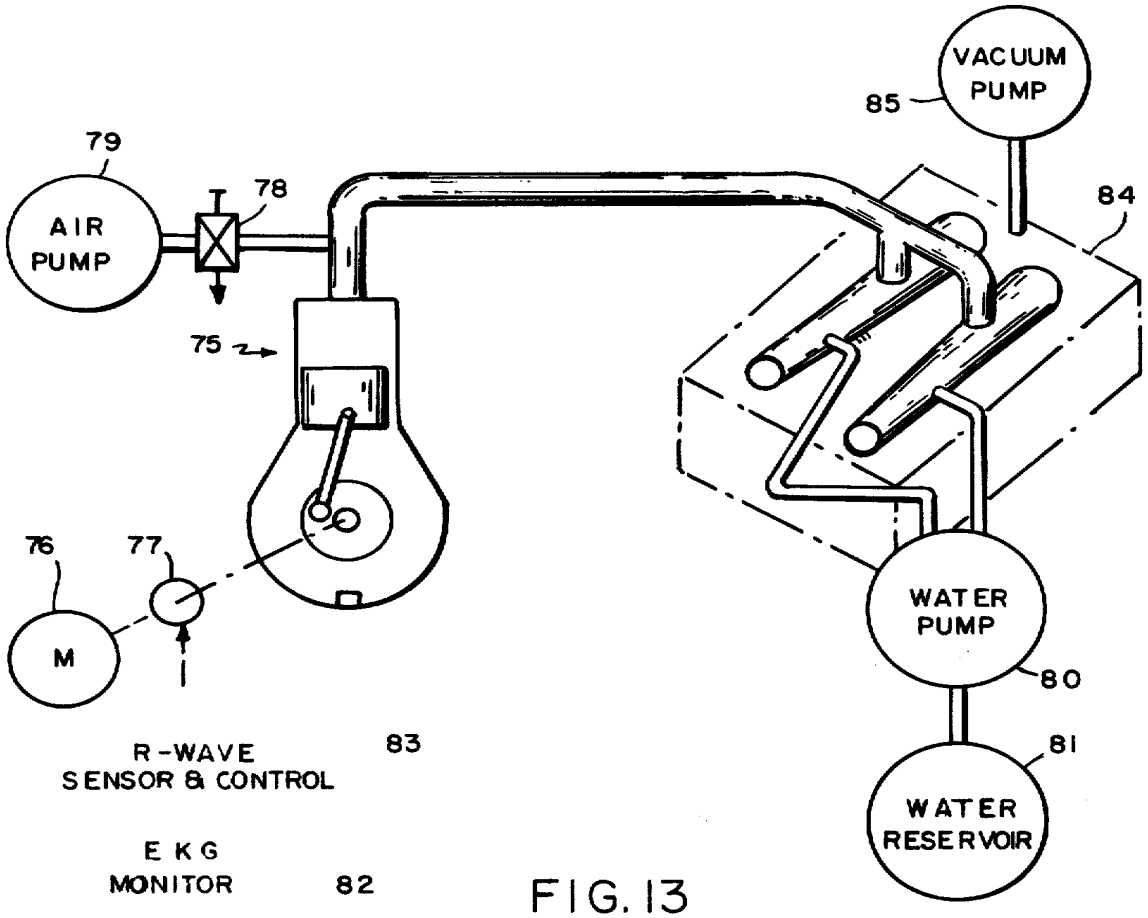

VACUUM
PUMP
85
79
78
84
AIR
PUMP
75
76
77
M
WATER
PUMP
80
81
WATER
RESERVOIR
R-WAVE
SENSOR & CONTROL
83
E K G
MONITOR
82

FIG. 13

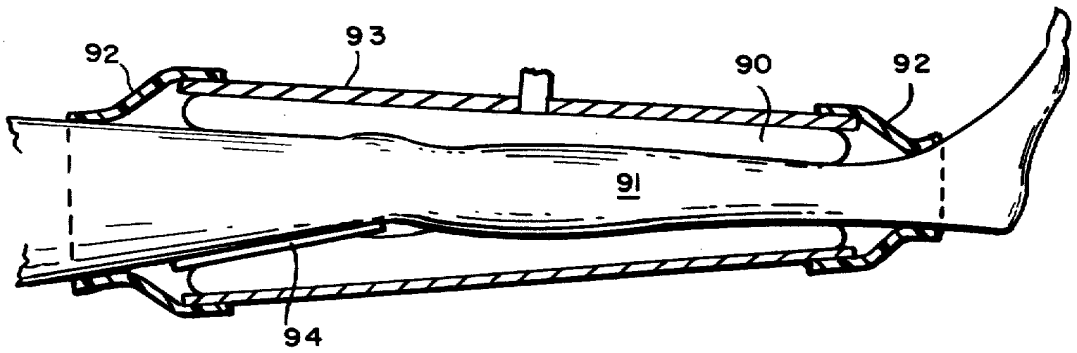


FIG. 14

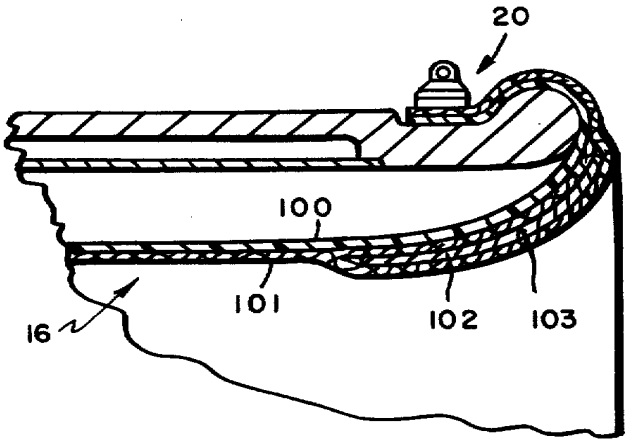


FIG. 15A

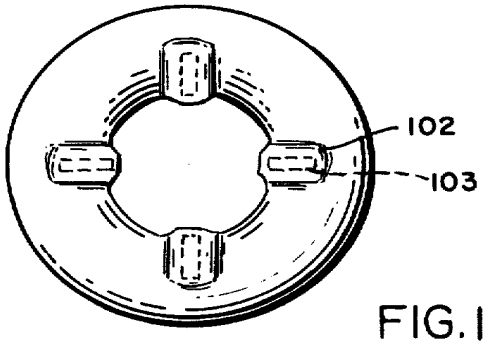


FIG. 15B

CARDIAC ASSIST APPARATUS

This invention relates generally to apparatus for assisting the circulation of blood in a human being and more particularly to an apparatus for doing so externally by the utilization of counter-pulsation techniques.

BACKGROUND OF THE INVENTION

Apparatus for providing external assistance in the circulation of blood in patients has been described in previously issued articles and patents, particularly U.S. Pat. No. 3,654,919 issued to W. C. Birtwell wherein a rigid housing encloses a portion of the patient's body, such as the legs, and a non-compressible hydraulic fluid is present within such housing. A suitable hydraulically actuated compression and decompression means is then utilized to cycle the pressure on said body portions via the non-compressible hydraulic fluid. Means are provided therein specifically to assure that the environment within the rigid housing is gas free so that no effective dead space is present and the efficiency of the compression and decompression energy transfer is maximized. Further, in the decompression portion of the cycle, a negative pressure is achieved immediately adjacent the body portion and means are provided for synchronously overriding the substmospheric pressure which is so obtained, such overriding being in appropriate synchronism with the patient's heartbeat.

A number of problems arise in the use of the device described in the above Birtwell patent. First of all, it is a relatively cumbersome structure to handle, the use of a non-compressible hydraulic fluid, such as water, making the overall apparatus quite heavy. Moreover, the hydraulic actuation equipment which is required to cause the compression and decompression flow of fluid within the housing must be placed relatively near the patient so as to avoid excessive hydraulic pressure drops along the fluid lines thereof, usually such actuator being placed on the table on which the patient himself lies, often substantially centrally located between the patient's legs, as shown in the patent.

Not only is such apparatus therein difficult to use because of the large size and weight of the rigid housings and the hydraulic fluid, together with the hydraulic actuation equipment therefor, but the presence of such elaborate equipment in the direct view of the patient may tend to produce an adverse psychological reaction on the part of the patient when the apparatus is being applied to the patient's limbs.

Moreover, the use of such rigid, fixed volume housing requires that they be made sufficiently large to fit the limbs of the largest patient to which the apparatus is expected to be applied. Thus, for patients with relatively small limbs, substantially more hydraulic liquid is required to fill the enclosure, a factor which only adds to the weight of the overall device and its difficulty in use.

In considering alternative structures for providing effective external assistance for the circulation of blood, the design thereof should provide for a reduction in the above disadvantages while still maintaining an effective energy transfer. The maintenance of such energy transfer must take into account the damping which may be present within the system, so that the effects thereof can be minimized and the overall efficiency of the system can be preserved.

Such damping can be broadly identified as arising from two major sources discussed in more detail below. A first source lies in the apparatus which comprises the system for producing the cyclic compression and decompression energy transfer to the patient's body. Such "system" damping can arise because of the distensibility of the housing which is used as well as the distensibility of the unsupported areas of the sealed portion of the system which contains the actuating fluid at the interface between the system and the portion of the patient's body to which the pulsating pressure is applied. Further, the instability of the shape of such sealed portion (i.e., the fact that such sealed portion does not retain its shape during the pulsating cycle) also contributes to the overall system damping. The compressibility of the actuating medium which gives rise to the presence of dead space within the housing also contributes to the system damping. Finally, both the presence of trapped air at various points within the system as well as the failure to provide an adequate contact between the sealed interface portion of the system and the patient's body can introduce additional damping into the system.

A second source of damping relates to the physical nature of the patient's body itself and can be best described as a form of "physiologic" damping. Such damping arises, for example, from the overall motion of the patient's body which can occur during the application of the pressure actuation system thereto. Additional factors which contribute to such physiologic damping include the displacement of body tissue, both in the areas to which the pressure is directly applied and in the areas adjacent thereto, and the compressibility of the body in those areas thereof which can contain gas, such as the abdomen and/or the thoracic cavity.

A primary consideration in the design of the structure disclosed in the above-mentioned Birtwell patent was the desire to reduce system damping which can arise because of the compressibility of the medium used to provide pressure actuation. Accordingly, such system used non-compressible hydraulic fluids, i.e., liquids, such as water, as the pressurizing medium in the sealed container at the interface with the patient's body, thereby necessitating the use of the hydraulic actuation and control system shown therein. While some consideration was given to the reduction of damping due to one or more of the other factors listed above (i.e., the utilization of a rigid, fixed volume housing, longitudinal tethering of the sealed container, etc.), little or no consideration was given to making the most effective use of the energy available, the hydraulic actuation system being arranged as an effectively open system where hydraulic fluid was continually supplied from the energy source. As a result, prime importance has been attached to the purported need to use non-compressible fluids, as opposed to compressible fluids, such as air, for pressure actuation and interface energy transfer so that damping at the interface of a rigid, fixed volume housing structure is minimized.

SUMMARY OF THE INVENTION

This invention, on the other hand, in one embodiment utilizes a compressible fluid, either alone or in combination with a non-compressible fluid, for energy transfer at the body interface. The use thereof provides an improved external assist apparatus which has the advantage of being lighter in weight and less cumbersome

to use than previously known apparatus, and further, which can be designed to reduce considerably the possibility of producing a traumatic experience for the patient. The effect of any increased interface damping which may result from the use of at least a partially compressible fluid medium is taken into account by utilizing a more efficient actuation system designed as a "closed" system wherein energy expended in transfer to the patient's body is effectively stored and returned to the system for reuse with a minimization of overall energy loss during operation. Such efficient use of energy overcomes the effects of increased damping due to the utilization of compressible fluids. Further, the effects of such increased damping can be overcome in other embodiments of the invention by utilizing housing units having adjustable volumes, the adjustment thereof being arranged to reduce the volume and, hence, the dead space which may give rise to damping at the interface of the medium with the patient's body.

More specifically, in one embodiment of the invention, for example, the housing is formed as a rigid, fixed volume type and the pressure is applied to the patient's body portion, such as the legs, through a medium which is at least partially in gaseous form. Because the pressure medium is, at least partly, a gas, such as air, the overall weight of the apparatus is reduced considerably and the compression and decompression cycle thereof can be actuated by the use of a pneumatic actuation system rather than a hydraulic system as in the prior art apparatus. Such a pneumatic actuator and control system can be placed at a position relatively remote from and out of the view of the patient without substantial pressure drops occurring in the pneumatic feed lines to the pressure applying medium. The use of a pneumatic actuation apparatus, which reduces the amount of equipment required to be located immediately adjacent the patient, thereby lessens the traumatic experience for the patient and provides more working space at the patient location for the medical personnel using the apparatus. Moreover, the reduction in weight makes the placement of the leg enclosure units on the patient much easier than with prior art devices. The pneumatic actuation system is designed so that some of the energy used to effect the desired pressure at the patient's limb is stored and reused so that the overall energy expenditure is at least comparable to that in the prior art structures which require hydraulic fluids for such purpose.

In still other embodiments of the apparatus of the invention utilizing such pneumatic actuation and control together with at least a partially gaseous pressure medium, the housing may be made of a rigid or semi-rigid material which is arranged to permit the formation of a variable volume of space within which the pressure medium is enclosed. Thus, the housing is designed to be so adjustable that a sufficiently small spatial volume can be achieved to reduce considerably the presence of dead space which may arise due to the compressibility of the gas. Moreover, the arrangement of a variable volume enclosure permits the configuration of such housings to be adjusted to patients of different sizes.

Particular embodiments of the invention are discussed in more detail below with the help of the accompanying drawings wherein

FIG. 1 shows a pictorial view of an overall system utilizing the apparatus of the invention;

FIG. 2 shows a view in longitudinal section of one embodiment of a body portion housing unit used in the apparatus of FIG. 1;

FIGS. 3 and 3A show both views in longitudinal and cross section of another embodiment of a body portion housing unit used in the apparatus of FIG. 1:

FIG. 4 shows a view in cross-section of the body portion housing unit of FIG. 2 taken along the lines 4—4 thereof;

FIG. 5 shows a view in cross-section of the body portion housing unit of FIG. 3 taken along the lines 5—5 thereof;

FIG. 6 shows a view in cross-section of a body portion housing unit utilizing one embodiment of a pressure medium comprising a gas-liquid combination;

FIG. 7 shows a view in cross-section of a body portion unit utilizing another embodiment of a gas-liquid pressure medium;

FIG. 8 shows a side elevational view of a body portion housing unit which has an adjustable configuration to permit the formation of a variable volume within;

FIG. 9 shows a view in cross-section of the body portion housing unit of FIG. 8 taken along the lines 9—9 thereof;

FIG. 10 shows another embodiment of a body portion housing unit utilizing a configuration of segmented cones;

FIG. 11 shows a view in cross-section of a portion of the housing unit shown in FIG. 10;

FIG. 12 shows a graph of one embodiment of the pressure waveform used in the system of the invention;

FIG. 13 shows a view, partially in block form and partially in diagrammatic form, of the pneumatic actuation system of the invention;

FIG. 14 shows a longitudinal section view of an alternate embodiment of the invention; and

FIGS. 15A and 15B show an alternative embodiment of the configuration shown in FIG. 2.

As shown in FIG. 1, the overall system in accordance with the invention comprises in one embodiment thereof a pair of leg units in the form of housings 10 which enclose a substantial portion of the legs of the patient to be treated. The leg units are generally formed to permit the lower leg from approximately the ankle region down to the foot to project outwardly from the lower end of the housing unit, the unit extending upwardly therefrom to the upper leg in the region of the thighs. Separate leg units may be used, or such units may be joined at their upper ends either by fixed connections to form a fixed angle with respect to each other or by pivotal connections so that such angle may be suitably varied as desired.

As described in more detail below, the leg units enclose a pressurizeable medium which acts as an interface between the surface of the legs of the patient within the housing and a pressure actuation and control system 11. The medium as discussed below can be either fully gaseous or at least partially gaseous and is actuated by a pneumatic pressure actuation system which cyclically feeds gas under pressure via tubings 12 to each of the leg units and then removes said gas by reversal of said pressure to sub-atmospheric levels in a cyclic fashion. Alternatively, the gas may be fed by a single tubing from the actuator and then supplied to each housing by a pair of branch tubings connected thereto by a suitable T-connection arrangement.

Accordingly, an appropriate compression and decompression of the patient's legs will occur so as to assist the circulation of the blood, the cyclical application thereof being in appropriate synchronism with the patient's heartbeat as described in the aforementioned Birtwell patent, and as described, for example, in the article "Support of the Systemic Circulation and Left Ventricular Assist by Synchronous Pulsation of Extramural Pressure," Birtwell et al., Vol. XI, Trans. Amer. Soc. Artif. Int. Organs, 1965.

One embodiment of leg units **10** is described in more detail in FIGS. **2** and **4** wherein it can be seen that each leg unit comprises a rigid housing **15** in a substantially frusto-conical shape, such housing in the embodiment described being made of aluminum or an appropriate rigid plastic material as desired. A flexible, fluid-tight material forms a sealed member **16** which is pressure expansible the material thereof being preferably non-distensible. The material is formed in a tubular shape and mounted within the rigid enclosure so as to completely enclose the major portion of the leg **17** of the patient (not shown), the surface of the plastic material generally conforming to the contour of the patient's leg. In the embodiment shown the flexible material is attached to the rigid housing by lapping the ends thereof over the rounded ends **18** of the housing so as to permit the overlapped ends to rest in notches **19** of the housing over which notches appropriate sealing rings **20** may be attached. As used herein the term "flexible material" may include thermosetting and thermoplastic elastomeric materials and may also include, for example, multi-layered materials, such as one having a first inner layer of distensible material and a second outer layer of a non-distensible material, such as one having a layer of rubber backed by a layer of cloth.

A fitting **21** is integrally formed in housing **15** to provide an opening **22** at the exterior surface of the housing which can be suitably connected to the pneumatic pressure actuation system **11** which supplies gas under pressure at above atmospheric pressure throughout a first portion of its cycle and which removes gas to create a subatmospheric pressure within the sealed member **16** during the remaining portion of its cycle.

The pressurizeable medium is introduced into the spatial volume between flexible sealed member **16** and the inner wall **23** of housing **15** so that as the pressure therein increases during the compression portion of the cycle the pressure medium presses against the patient's leg as desired. A perforated tubular member **24** is attached by suitable means such as an adhesive to shoulders **15A** at the interior of housing **15** in the space between member **16** and housing **15** at about a position midway therebetween. Member **24** may be a rigid plastic material, for example, and prevents the flexible member from collapsing completely against and adhering to the interior wall of housing **15** during the decompression portion of the cycle, which collapse may cause an effective but undesirable valving action which would prevent an efficient transfer of oscillatory energy from the actuator to the leg. Member **16** can be made of any suitable thin metallic or plastic material, such as aluminum or acetal, for example.

In the embodiment shown in FIGS. **3**, **3A** and **5**, the member which contains the pressurizeable medium is formed separately from the rigid housing itself. As can be seen therein a flexible, tubular sealed container **25** is made of a suitable flexible material such as nylon-neoprene cloth, for example. In a collapsed state the container may be folded flat or rolled up into a compact annular shape. When the apparatus is to be used, the container **25** is suitably unfurled and placed, as shown in FIG. **3**, within the housing over the patient's leg. The container has an appropriate integrally-formed fitting **26** which is inserted through a suitable opening in a rigid housing **27** and which is adapted to be connected to a pressure actuation source. The flexible container **25** is thereby enclosed by the rigid housing **27** which as seen in FIG. **5** can be constructed for this purpose in two pieces, **27A** and **27B**, which are hingedly connected. During use, the major portion of the patient's leg is encased in flexible container **25**, is placed in lower piece **27B** and the upper piece **27A** is rotated to a closed position and clamped to the lower piece by any suitable conventional clamping mechanism **28** to form a rigid housing around container **25**.

In order to prevent any valving action in the embodiment of FIG. **3** appropriate manifolding means may be used within the interior thereof to prevent collapse of the outer surface thereof against the inner surface adjacent the wall of the housing. One suitable manifolding means as shown in FIG. **3** can comprise an interior layer of rubber material **29** adjacent the housing wall, such layer having a plurality of projections **29A** extending toward the interior of container **25** as shown.

In the embodiments discussed above with reference to FIGS. **1–5**, as well as in the embodiments of the prior art, a longitudinal force difference tends to exist along the patient's legs during operation of the system because of the difference in the cross-sectional area at the patient's thighs and that at the patient's ankles. Such force differential causes the inner wall of the sealed members of the apparatus (i.e., the direct interface of the inner wall of flexible members **16** or **25** in contact with the patient's leg in FIGS. **2** and **3**, for example) to move longitudinally with respect to the outer wall thereof (i.e., the housing wall in FIG. **2** or the outer wall of flexible container **25** in FIG. **3** which is in contact with the housing). As a result, such movement tends to move the legs and, hence, the entire body of the patient outwardly from the housing and, in effect, to forcibly eject the patient from the housing units, thereby reducing the effectiveness of the system to perform its task as well as producing discomfort and a further traumatic effect on the patient.

In order to overcome such movement it is desirable to longitudinally tether at least a portion of the inner wall of the sealed member to the housing (FIG. **2**) or to the outer wall thereof adjacent the housing (FIG. **3**). It has been found that if such tethering is effected, for example, along two or four parallel lines near each end of the housing, longitudinal movement of the inner wall of container **25** is reduced considerably. Four such tether lines **25A** are shown in an exemplary embodiment of FIGS. **3** and **3A**. Although the tethered portions may extend the entire length of the housing, it is not found necessary to do so in all applications, and tethering at the ends thereof may be sufficient. Accordingly, they may be arranged in preferred embodiments, for example, to extend inwardly from each end thereof to lengths of about 10–20 percent of the total housing length. Moreover, additional tethered portions may be used at other positions in addition to the ends thereof, if desired.

In the embodiment of FIGS. **2** and **24** the tethered portions **16A** of the inner wall of container **16** may be arranged to be suitably tethered to the rounded end **18** of the housing and to the ends of perforated member **24** as shown therein. Alternatively, in FIG. **2** the ends of the sealed member **16** may be effectively tethered without the necessity for adhering member **16** to the housing wall. For example, FIGS. **15A** and **15B** show an alternative structure wherein the flexible member is formed of a multi-layer material in which a first inner layer **100** is rubber and a second outer layer **101** is cloth. A plurality of generally longitudinally directed pockets **102** are formed between the layers at each end thereof (for simplicity only a view of one end is shown in FIG. **15B** and only a part thereof in FIG. **15A**). The extreme end of member **16** is held by the sealing ring **20** in the manner discussed above with reference to FIG. **2** and the pockets **102** extend from a point within the interior of the housing to a point approximately adjacent the region where member **16** overlaps the rounded end **18** of the housing. A plurality of spring-like, or semi-rigid, stays **103** are inserted in the plurality of pockets at each end of flexible member **16** so as to project inwardly of the housing. The use of such stays tends to prevent longitudinal motion of the ends of flexible member **16** relative to the housing **16** so that such ends are effectively tethered thereby.

The pressurization medium in the above embodiments can be either fully gaseous or may be a gas-liquid combination depending upon the application which is desired. In permanent installations, for example, where sufficient power is available for the use of relatively large motors (e.g., over 1 horsepower), the medium can be completely gaseous and dead space problems can be overcome by installing a suitably sized motor to operate under all expected dead-space conditions. Even in portable, or less permanently installed, apparatus a completely gaseous medium can often be used relatively effectively with smaller motors of less than 1 horsepower because of the effective utilization of energy brought about by the use of a closed pneumatic actuation system as discussed further below.

A further advantage of the use of pneumatic systems in this regard is that the compressible gaseous medium can inherently achieve the desired negative pressures with less expenditure of energy from the energy input source than is required when using an hydraulic medium, such as water. Thus, the use of a gaseous medium eliminates the static head which is present when using an hydraulic medium which completely surrounds the patient's limb. In the latter case the positive head must be overcome before any negative pressure is obtained. Such an advantage in using a pneumatic system then tends further to offset any disadvantage which may arise because of any increase in damping due to the use of a compressible gaseous medium. This advantage can still be obtained even when using a combined gas/liquid medium, particularly with the system discussed below with reference to FIG. **6** where the liquid portion thereof is maintained substantially below the patient's leg so that no static head is present.

If the dead space which exists due to the compressibility of the gaseous medium tends to prevent the creation of sufficient pressures as required and if sufficiently large actuator systems are not available to overcome such problem, such dead space may be reduced by using an apparatus which utilizes a combined gas-liquid pressure medium as shown with reference to FIGS. **6** and **7**. As can be seen in FIG. **6**, for example, a housing **30** of the form shown in FIG. **4**, for example, has a sealed flexible container **31** which substantially conforms to the patient's leg and has contained therein a liquid medium **32** and a gaseous medium **33** in direct contact therewith. In a practical embodiment, for example, the liquid medium such as water, may preferably be approximately 50 percent, or more, of the volume within the housing. A pneumatic actuation system as shown in FIG. **1** is then appropriately connected to fitting **34** so that the gaseous medium, such as air, can be pressurized, the liquid medium taking up substantially most of the dead space that may occur within the sealed enclosure due to the compressibility of the gaseous medium. In this way, a relatively efficient transfer of pressure to the leg can be achieved.

Another embodiment of a combined gas-liquid pressurizeable medium is shown in FIG. **7**. As can be seen therein, the liquid medium **42** and the gas medium **43** are separated from each other, the liquid medium being placed in a flexible sealed container **41** which encircles the leg of the patient and forms the direct pressure interface with the patient's body. The gas coupling medium **43** is inserted into the housing **40** between the sealed liquid container **41** and the interior surface of housing **40**. An appropriate fitting **44** is connected to a pneumatic actuation system for inserting and withdrawing gas above and below atmospheric pressure, which gas pressure variations are coupled via gas medium **43** to the liquid medium **42** and then to the patient's leg for providing the cyclic compression and decompression action required.

While the use of rigid, fixed volume housing units as shown in FIGS. **2–7** are useful in many applications, it is desirable in still other applications to provide for rigid or semi-rigid housings having adjustable volumes particularly for permitting an adjustment thereof when used with patients having different limb sizes, which adjustment can also be used to reduce any dead space which may exist when such structure is used with a completely or partially compressible medium. One embodiment of such a variable volume housing is shown in FIGS. **8** and **9**, the diameter of which can be varied at varous points along the length thereof. For example, the housing **50** may be made in the form of a collapsible, or adjustable, sheet of metallic material, such as sheet aluminum, which is formed in an overlapping manner into a substantially frusto-conical shape. A plurality of adjustable bands, or rings **51** are placed at selected positions along the length thereof. The patient's leg is inserted into the housing when the bands are in a relatively loose condition so that an effectively large diameter housing is formed. The bands are then tightened so as to reduce the volume of the space between the housing and the patient's limb in which a sealed container **52** fits. Thus, the dead space, which ordinarily may be present when a compressible medium, such as air, is completely or partially used as the pressurizeable medium can be minimized no matter what the size of the patient's leg. Accordingly, the efficiency of the overall pneumatic actuation system can be increased thereby enhancing the capability of the system to operate even with pressure actuation systems of relatively low power.

The variable volume structure shown can also use a completely non-compressible medium. In such a case,

because the variable volume housing structure permits a closer conformity of the housing to the legs of the patient, less hydraulic fluid is required than in those fixed volume structures of the prior art so that a consequent overall reduction in weight of the portion of the apparatus at the patient's legs occurs. Further, the volume adjustments permit a closer conformity of the overall sealed container to the patient's body and tends to reduce the unsupported annular end regions of the flexible container and, accordingly, the damping due thereto. Further, as the housing volume is reduced, a better conformability of the tethered portions of the sealed container to the patient's body results.

Another embodiment of a rigid, or semi-rigid housing which can be utilized to make the most efficient use of the apparatus of the invention for different size patients is shown in FIG. **10.** As can be seen therein, a relatively large frusto-conically shaped housing **60** can be formed from a plurality of segmented frusto-conical members **61** each of which can be suitably attached and detached to adjacent of said members having corresponding diameters. In the process of use, a selectable portion of the overall housing can be formed in accordance with the size of the patient's leg. For example, in the illustrated embodiment of a segmented housing of FIG. **10,** seven separable segments A–G are depicted, segments A, B, C, E, F, G being of approximately the same length and segment D being approximately three times larger in the specific embodiment shown. The overall housing with all segments attached together is made available for use with a patient. For use with a patient having a relatively small diameter leg, sections A, B, C, D and E may be selected and the segmented sections F and G may be detached therefrom. For a medium sized leg, it may be desirable to utilize only sections B, C, D, E and F with sections A and G detached therefrom. For relatively large legs it may be desirable to use sections C, D, E, F and G with sections A and B detached therefrom. Accordingly, the amount of dead space which is present for use in a system using a complete or partial gaseous medium can be minimized by the appropriate selection of segments in accordance with the size of a patient's leg. The segments shown in FIG. **10** can be attached by appropriate means as shown in the exemplary embodiment of FIG. **11.** As seen therein if housing segments, each of the type shown in FIG. **2,** are used the flexible containers **62A** or **62B** of adjacent segments are lapped over the corresponding ends **63A** and **63B** thereof to rest in notches **64A** and **64B**. Clamp members **65A** and **65B** have first flanges **66A** and **66B** which rest in notches **64A** and **64B** respectively, above the lapped ends of the flexible containers therein. Upright flanges **67A** and **67B** lie adjacent each other at the junction of the housing segments and are appropriately clamped to each other at suitable points located on the periphery of the housings via threaded bolts **68** inserted through threaded openings in the upright flanges. The flanges **66A** and **66B** are retained in the notched ends of the housing segments by suitable clamping bands **69A** and **69B**, respectively, as shown.

In a preferred embodiment of the invention the pneumatic actuation system which is utilized will provide an effective sinusoidal pressure wave form **70** as shown in FIG. **12.** As can be seen therein, the pressure can vary in a particular embodiment from a minimum valve within a preferred range of approximately +25 mm. Hg. to −50 mm. Hg., although such minimum value may be set otherwise in some applications, to a maximum value within a preferred range of approximately 200 mm. Hg. to 250 mm. Hg., although such maximum value also may be set otherwise in some applications. The rise time is defined as the time the pressure rises from a low value equal to 10 percent of the peak-to-peak value thereof to a value equal to 90 percent of such peak-to-peak value, with the fall time being similarly defined as the time the pressure decreases from 90 percent of its peak-to-peak value to 10 percent thereof. A preferred rise time and a preferred fall time is usually set within a range of 80–150 milliseconds in each case.

The time duration of the pulsating portion of the wave form is defined as the time for the pressure wave form to rise from a low value at 10 percent of its peak-to-peak value to a time when it has passed through its positive peak value to a value of 90 percent of the peak-to-peak value thereof. Such time may preferably lie within a range of about 200–500 milliseconds.

Although a sine wave is shown in FIG. **12,** the system is not limited to such a wave form. A square wave configuration may be acceptable in some applications if the discrete changes thereof do not cause adverse effects on the patient. Other wave shapes may be devised also for such purpose.

A pneumatic actuation system for achieving an appropriate pressure wave form is shown in FIG. **13** wherein it can be seen that a suitably sized crank driven piston **75,** fitted with conventional low friction, low hysteresis seals and driven by a variable speed gear motor **76** through an appropriate clutch/brake combination **77,** provides a means for producing synchronous pneumatic pressure pulses of the wave shape described above, such pressure pulses being applied to the coupling medium at the interface with the patient's limb to create the desired hemodynamic results. Appropriate and known means can be utilized to adjust the amplitude of the pressure pulse and the relationship of the positive and negative peak pressure amplitudes with ambient (room atmospheric) pressure.

Thus, if the atmospheric pressure volume of the medium in the pneumatic actuation system is such that the piston stroke is at its mid-stroke position, driving the piston in one direction (forward) will create a positive pressure and driving it in the opposite direction (backward) will create a negative pressure. Any appropriate combination of positive and negative peak pressures can be arranged within the total pressure differential capability of the pump system and can be selected for an individual patient by adjustment of the total volume of fluid in the system (often referred to as the "charge" on the system) to produce the optimum hemodynamic results which are desired. Such volume adjustment can be made by adjustment of valve **78** which supplies air from air pump **79** to the system. In a system which uses an air/liquid combination or in a variable volume system which uses a liquid medium alone, the hydraulic liquid can be supplied from a liquid reservoir **81** via a suitable pump **80.** Appropriate synchronism with the patient's heartbeat can then be provided by suitable monitoring of the patient's EKG by monitor **82,** a sensing of the R wave of the patient's heartbeat to provide suitable control of the operation of the clutch/brake combination **77** and, accordingly, of the piston motion of the actuation system relative to the R wave, as shown by the R-wave sensor and control device **83.** Such syn-

chronization and control is explained in more detail, for example, in the article cited above.

The effectiveness in achieving a negative pressure at the patient's body is dependent upon how good a seal is maintained between the inner surface of the sealed container containing the energy coupling medium and the surface of the patient's limbs during the negative portion of the pulsation cycle. Such seal can be maintained by the use of an adhesive compound on the surface of the sealed container between the container and the limb. However, such a method may be impractical or inappropriate in many situations.

Another method for providing such a seal is to evacuate all of the air between the limb and the sealed container outer surface, such evacuation being maintained against the levels of those peak negative pressures being created by the pneumatic actuation system applied through the actuation fluid in the sealed container. Thus, a continuous suction can be created in the space between the limb and the sealed container by an external evacuation device. One method of achieving this is to enclose the legs and housing units of the system by a vacuum enclosure **84** as shown by the dashed line in FIG. **13**, such enclosure being appropriately evacuated by an external vacuum pump **85** which creates a zone of sub-atmospheric pressure below that expected at the lowest region of the pressure actuation curve of FIG. **12** around such housing system.

A further method of providing an appropriate seal is to arrange for an effective self-evacuation system for such purpose, thereby eliminating the need for a vacuum enclosure and external vacuum pump. Since the sub-atmospheric pressure in the space between the sealed container and the patient's body is required only during the time when the pressure wave form is below atmospheric pressure, such time being a relatively short part of the overall pressure cycle, there need not be a requirement for a constant negative pressure as would exist in the above described externally actuated evacuation system. Such a self-evacuation system is shown in FIG. **14**. As seen therein, the ends of the space between the sealed container **90** and the patient's legs **91** at the ankles and at the thighs are fitted with passive one-way valves **92** which permit the expulsion of air from such space to the atmosphere but which prevent the intake of air from the atmosphere to such space. Such valves may be in the form of thin rubber rings placed over the ends of the housing **93**, the free ends thereof being held tightly against the patient's ankles and thighs when applied. During each positive pressure portion of the pressure wave form, the ends of the one-way valves are opened and substantially all of the air in the space between the leg and the sealed container is expelled therefrom. During the negative portions of the pressure wave form the ends thereof are closed and an effective evacuation of the space between the limb and container is maintained. While the air is vented to the atmosphere in the embodiment shown in FIG. **14** the output valves may alternatively be attached to suitable suction pumps to further insure that no air will leak back into such space during the negative pressure phase of the pressure wave form. In order to prevent valving of the container a suitable manifold means **94** may be placed within the container. Such manifold means may be in the form of a rigid tubular structure preferably extending from the region below the knee to the end of the housing. The manifold provides a passageway for any trapped air that may be present, such trapped air being most likely to be present at such knee region. In those embodiments which utilize tethers, as discussed above, the presence of the tethers may be sufficient to provide such passageways without the need for such an additional manifold means.

The above description shows various embodiments of the invention, although other embodiments within the scope of the invention may occur to those in the art. Hence, the invention is not to be construed as limited to the particular embodiments shown herein except as defined by the appended claims.

The following U.S. Pat. Nos. were obtained by a patent search: 1,608,239, 2,113,253, 2,168,611, 2,345,073, 2,361,242, 3,179,106, 3,268,711, 3,288,132, 3,292,613, 3,303,841, 3,307,533, 3,329,142, 3,403,673, 3,411,496, 3,548,809, 3,599,631, 3,651,801, 3,654,919, 3,659,593, 3,674,018, 3,693,627.

What is claimed is:

1. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion which is in gaseous form, enclosed in a flexible sealed member which is pressure expansible and positioned between said pressure actuation means and said portion of the patient's body, at least a part of said sealed member being in contact with said body portion, a first portion of said sealed member being formed of a flexible material sealably clamped to the ends of said housing and a second portion thereof being formed by said housing, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion;

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat; and

means for preventing said flexible material from collapsing against said housing during the decompression portion of the cyclical application of said pressure.

2. An apparatus in accordance with claim **1** wherein at least selected portions of said flexible material are tethered to portions of said housing to prevent the tendency for relative movement between said flexible material and said housing.

3. An apparatus in accordance with claim **2** wherein said flexible material is tethered to said housing substantially at the ends thereof.

4. An apparatus in accordance with claim **1** wherein said last-named means is a perforated tubular member positioned within said housing between said housing and said flexible material.

5. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion of which is in gaseous form, enclosed in a flexible sealed member which is pressure expansible and positioned between said pressure actuation means and said portion of the patient's body, said sealed member being a flexible tubular means formed independently of said housing, said sealed member being positioned during operation of said apparatus between the inner wall of said housing and said body portion to flexibly enclose said body portion, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion;

means for preventing the walls of said flexible sealed member from collapsing against each other during the decompression portion of the cyclical application of said pressure; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

6. An apparatus in accordance with claim **5** wherein portions of the inner wall of said flexible sealed member adjacent said body portion are tethered to portions of the outer wall thereof adjacent said housing to prevent the tendency for relative movement of said inner and outer walls.

7. An apparatus in accordance with claim **6** wherein said tethered portions are substantially at the ends of said flexible sealed member.

8. An apparatus in accordance with claim **5** wherein said said preventing means means comprises a flexible means having a plurality of projections extending into the interior of said sealed member.

9. apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body, said housing comprising

a pair of hingedly connected portions pivotally movable relative to each other from an open to a closed position;

means for clamping said portions together in said closed position;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion of which is in gaseous form, enclosed in a flexible sealed member which is pressure expansible, at least a part of said sealed member being in contact with said body portion, and positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

10. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium enclosed in a flexible sealed member which is pressure expansible and positioned between said pressure actuation means and said portion of the patient's body, at least a part of said sealed member being in contact with said body portion, said pressure medium being a combination of a gaseous material and a liquid material placed within said flexible sealed member in contact with each other and further being responsive to said pneumatic pressure actuation means to apply pressure to said body portion; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

11. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion;

said pressure medium being a combination of a gaseous material and a liquid material;

said liquid material being placed within a first flexible sealed member in contact with said body portion;

said gaseous material being placed within the said housing between said first flexible sealed member and said housing;

said pneumatic pressure actuation means being coupled to said gaseous material; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

12. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion;

said pressure medium being a combination of a gaseous material and a liquid material;

said gaseous material being placed within a flexible sealed member in contact with and enclosing said body portion;

said liquid material being placed within said housing between said flexible gaseous container and said housing;

said pneumatic actuation means being coupled to said liquid material; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

13. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means for enclosing a portion of said patient's body, said housing means including means for adjusting the volume enclosed thereby to provide for a variable volume when enclosing said body portion;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion of which is in gaseous form, positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion; and means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

14. Apparatus in accordance with claim **13** wherein said pressure medium is enclosed in a flexible sealed member which is pressure expansible, at least a part of said sealed member being in contact with said body portion.

15. Apparatus in accordance with claim **14** wherein a first portion of said sealed member is formed of a flexible material sealably clamped to the ends of said housing and a second portion thereof is formed by said housing.

16. Apparatus in accordance with claim **14** wherein said sealed member is a flexible tubular means formed independently of said housing, said sealed member being positioned during operation of said apparatus between the inner wall of said housing and said body portion to flexibly enclose said body portion.

17. Apparatus in accordance with claim **13** wherein said pressure medium is a combination of a gaseous material and a liquid material placed within a flexible sealed member in contact with each other.

18. Apparatus in accordance with claim **13** wherein said pressure medium is a combination of a gaseous material and a liquid material;

said liquid material being placed within a first flexible sealed member in contact with said body portion;

said gaseous material is placed within the said housing between said flexible sealed member and said housing; and

said pneumatic pressure actuation means is coupled to said gaseous material.

19. Apparatus in accordance with claim **13** wherein said pressure medium is a combination of a gaseous material and a liquid material;

said gaseous material being contained within a flexible sealed member in contact with and enclosing said body portion;

said liquid material being placed within said housing between said flexible sealed member and said housing; and

said pneumatic actuation means is coupled to said liquid material.

20. An apparatus in accordance with claim **13** wherein

said housing is formed of sheet metal being arranged in a substantially frusto-conical shape and having overlapping portions along the longitudinal direction thereof; and

said adjusting means providing for the adjustment of the amount of overlap of said overlapping portions to permit adjustment of the volume enclosed thereby.

21. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means for enclosing a portion of said patient's body;

means for adjusting the volume enclosed by said housing means to provide for a variable volume when enclosing said body portion;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

pressure actuation means;

a liquid pressure medium enclosed in a flexible sealed member which is pressure expansible, said sealed member being positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pressure actuation means to apply pressure to said body portion; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

22. Apparatus in accordance with claim **21** wherein said pressure actuation means is a hydraulic pressure actuation means coupled to said liquid material in said flexible sealed member.

23. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means for enclosing a portion of said patient's body;

said housing means comprising a plurality of frusto-conical segments and further including

means for affixing a selected number of said segments to one another to form a substantially rigid housing of a selected length and having openings at the ends thereof of predetermined diameters for use with body portions of different sizes;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion of which is in gaseous form, positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

24. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion of which is in gaseous form, positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion;

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat;

an evacuation chamber enclosing said housing means and the body portion enclosed by said housing; and

vacuum pump means for maintaining a pressure within said evacuation chamber at a level below the lowest pressure achieved during the decompression portion of the cyclical pressure applied to said body portion.

25. An apparatus in accordance with claim **23** wherein said one-way valve comprises a flexible ring positioned over the ends of said housing, the free ends of said ring being held tightly against the body portions of said patient at said ends.

26. An apparatus in accordance with claim **25** and further including manifold means for conveying trapped air from the interior of said housing to said end regions thereof.

27. An apparatus in accordance with claim **24** wherein the ends of said member include

a plurality of pockets formed therein between said layers; and

a substantially rigid stay positioned in each of said pockets;

whereby the tendency for said flexible sealed member to move relative to said housing tends to be reduced.

28. An apparatus in accordance with claim **9** and further including one-way valve means positioned at the common ends of said housing and said flexible sealed member to permit the expulsion of air from the region at said ends during the compression portion of said cyclically applied pressure and to prevent the intake of air into said region during the decompression portion of said cyclically applied pressure, thereby to maintain an effective evacuation of air in said region during said decompression portion.

29. An apparatus in accordance with claim **1** wherein said flexible sealed member is formed of a first layer of rubberlike material and a second layer of cloth-like material.

* * * * *

United States Patent [19]

McGrath

[11] **3,896,794**

[45] **July 29, 1975**

[54] **VENOUS FLOW STIMULATOR**

[75] Inventor: **John Alan McGrath**, Harlow, England

[73] Assignee: **The British Oxygen Company Limited**, London, England

[22] Filed: **Dec. 14, 1973**

[21] Appl. No.: **424,813**

[52] **U.S. Cl.** ..... **128/24 R**

[51] **Int. Cl.** **A61h 1/00**

[58] **Field of Search** ..... 128/24 R, 64, DIG. 10, 128/DIG. 20, 325–327

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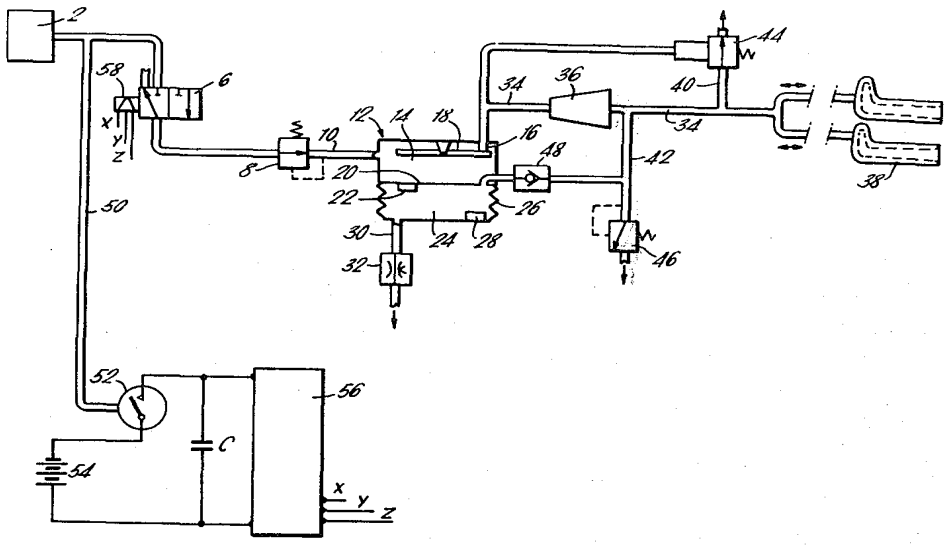
Primary Examiner—Lawrence W. Trapp

Attorney, Agent, or Firm—Dennison, Dennison, Townshend & Meserole

[57] **ABSTRACT**

Apparatus for automatically inflating and deflating, in a predetermined pressure cycle, at least one double-walled pneumatic boot fitted to the lower limb of a patient undergoing surgery.

12 Claims, 4 Drawing Figures



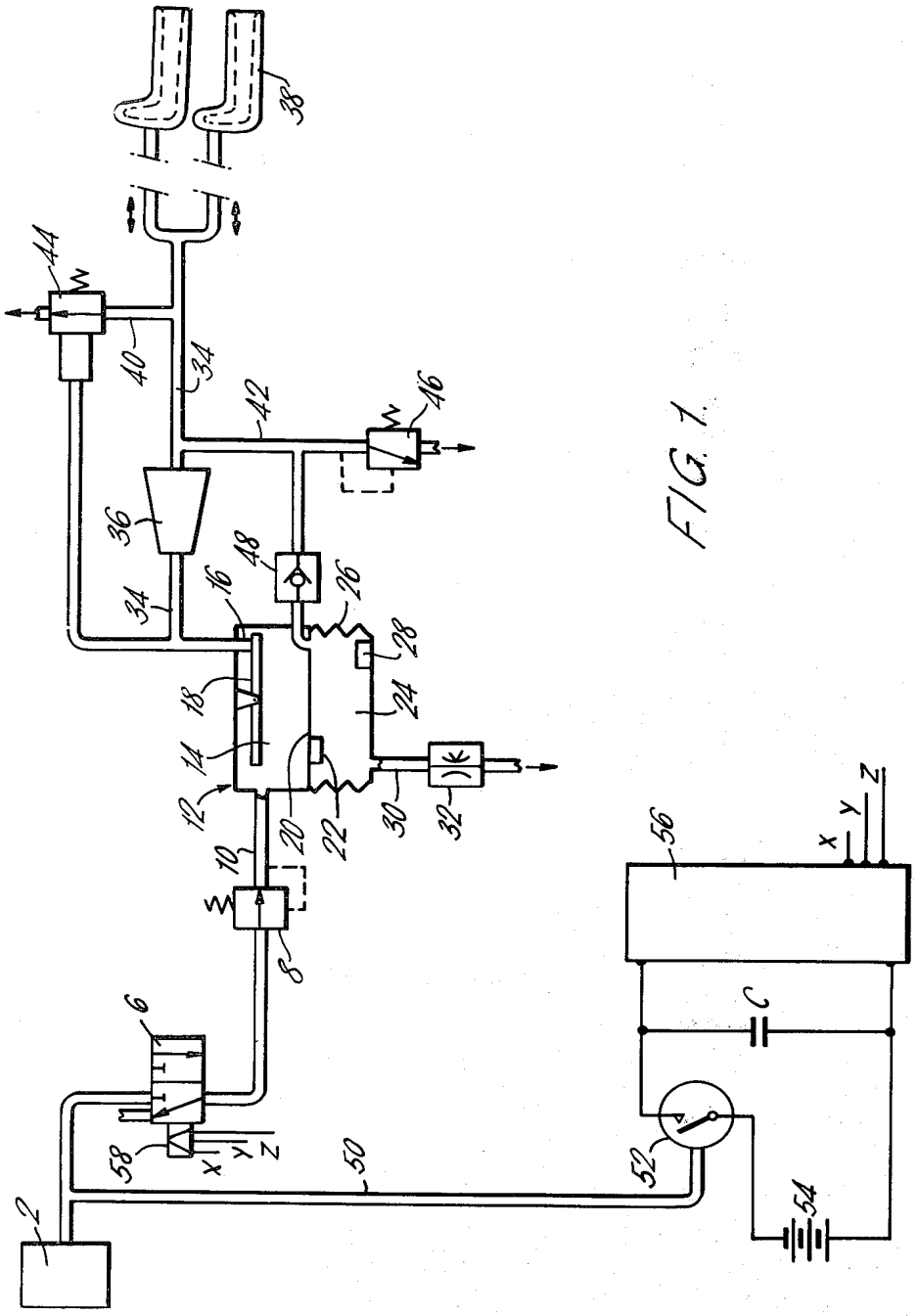

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FIG. 1.

FIG. 2.

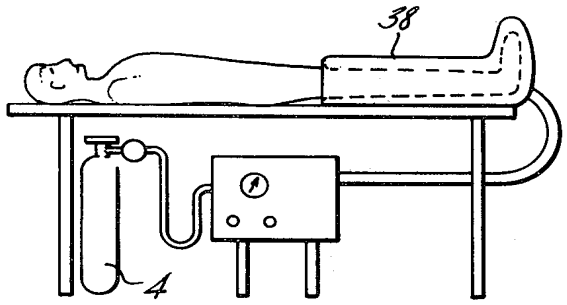

FIG. 3.

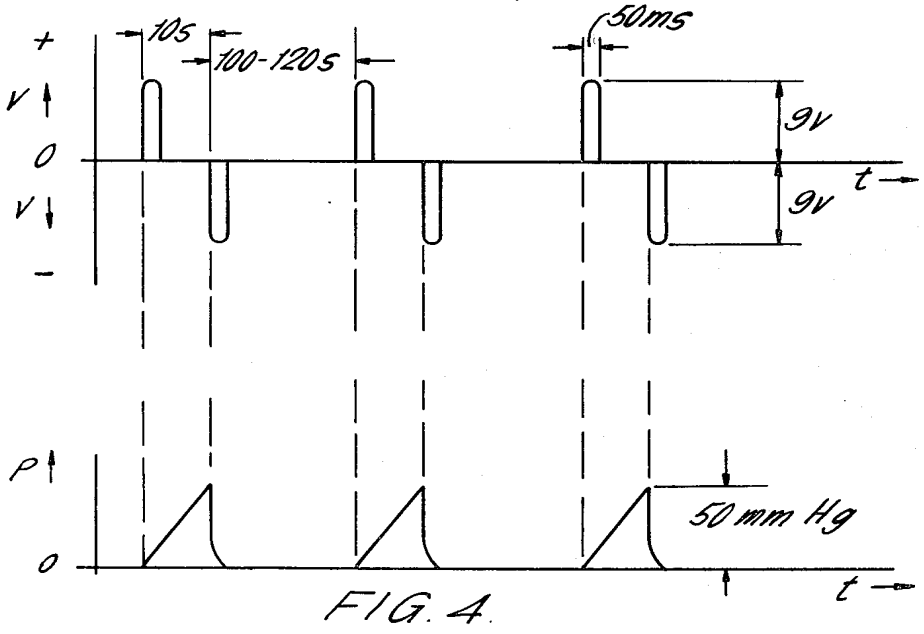

FIG. 4.

VENOUS FLOW STIMULATOR

This application relates to a venous flow stimulator, by which is meant a device used in some surgical operations to apply pulsating pneumatic pressure to the legs of a patient while undergoing surgery, in order to prevent the occurrence of post-operative deep venous thrombosis.

A known venous flow stimulator includes an electrically driven pump connected to one or a pair of inflatable pressure applicators (or pneumatic boots) adapted to be positioned around the patient's legs and feet. Pressure is applied (and released periodically) to the calf muscles of the legs of the patient by means of the boots so as to prevent stasis of blood flow in the deep veins of the legs. This reduces the risk of deep venous thrombosis occurring.

It is necessary to use the known form of venous flow stimulator to treat a patient throughout the preoperative, operative and postoperative period, treatment ceasing when the patient is ready to get out of bed. Each patient requires a machine for a relatively long period, and post-operatively the treatment may cause him discomfort and apprehension. Because the treatment is prolonged a considerable number of machines have to be employed and surgeons are reluctant to bring them into general use.

It is the aim of the present invention to provide an improved venous flow stimulator giving more effective treatment to enable the period of treatment to be reduced to that taken up by the surgical operation itself, so that the venous flow stimulator can therefore be essentially an apparatus for use only in the operating theatre.

According to the present invention there is provided a venous flow stimulator which is as claimed in the appended claims.

The venous flow stimulator of the present invention will now be described by way of example with reference to the accompanying drawings, in which:

FIG. 1 is a schema of one form of flow stimulator of the present invention;

FIG. 2 is a diagrammatic view of the stimulator in position during a surgical operation;

FIG. 3 is a graph of voltage v. time for the electrical pulses controlling operation of the stimulator, and

FIG. 4 is a graph of pressure v. time for the pneumatic pulses supplied by the stimulator to the boots encasing the patient's legs.

The venous flow stimulator shown in FIG. 1 includes a source 2 of pressurised gas usually in the form of the portable cylinder 4 shown in FIG. 2 leading through a solenoid-operated valve 6 to a flow regulator 8 (for example, of the type described in our UK patent specification No. 1,039,528). The flow regulator 8 leads through conduit 10, to a device 12 adapted to generate pulses of pressurised gas.

The device 12 has a gas supply chamber 14 of which an outlet 16 is controlled by a rocker valve 18. One wall of chamber 14 is formed by a diaphragm 20 carrying a permanent magnet 22. The device 12 also has a control chamber 24 formed by bellows 26, of which the end wall carries a second permanent magnet 28 and a conduit 30 leading to an adjustable bleed valve 32. Extending from the device 12 is a conduit 34 in which is positioned an injector 36. The injector is adapted to receive gas under high pressure from conduit 34 and dilute it substantially with air from the atmosphere in order to produce larger volumes of gas at lower pressure suitable for pressurising both boots 38 fitted to the feet and legs of the patient.

Downstream of the injector 36 the conduit 34 leads to two further conduits 40 and 42. The conduit 40 leads to the inlet of a pneumatically operated exhaust valve 44, while the conduit 42 leads to a pressure-relief valve 46 and to the interior of chamber 24 through a non-return valve 48.

Operation of the device 12 is governed by the pivotal position of rocker 18, which is in turn controlled by the relative positions of magents 22 and 28. The rocker 18 is of a soft magnetic material, such as Swedish iron, so that the rocker is able to be pivoted about its fulcrum when one or other of the magnets becomes dominant. As magnet 22 is positioned on the stationary diaphragm 20, the force it applies on rocket 18 in the valve-closing direction is substantially constant. Because the magnet 28 is positioned on the movable end wall of bellows 26, the magnet 28 is movable between two limit positions, in one of which its magnetic field overcomes that exerted on rocker 18 by magnet 22 and forces the rocker to pivot in the valve-opening direction. In the other limit position the magnetic field produced by magnet 28 falls below that exerted on rocket 18 by magnet 22 thus causing the rocker to be moved in the valve-closing direction.

A conduit 50 is pressurised from source 2 and leads to a pressure switch 52 which, when closed, causes a battery 54 to be connected across a capacitor C and across the input terminals of an electronic timer 56 having three outlets (labelled X, Y and Z) which are connected to respective terminals on a solenoid 58 controlling operation of valve 6.

The detailed circuitry of timer 56 is not described in this specification, but it is based on the use of digital integrated circuitry of the COS/MOS type. In particular, although this is not shown in the drawings or described herein in any greater detail, the timer includes a square-wave oscillator adapted to be energised by battery 54. The output of the oscillator is fed through a pulse-shaping circuit to a solid state switching circuit. Both the oscillator and pulse-shaper consist of two input, quadded NOR gates, which are available commercially, one form thereof being sold by RCA as an item in their COS/MOS CD4000A series of integrated circuits. The various components of these integrated circuits are interconnected through suitably rated electrical components to derive an output having the characteristics shown in FIG. 3 of the accompanying drawings. In a typical output, there is a positive-going pulse of 9 V amplitude and lasting 50 ms, followed after an interval of about 10 *s* by a negative-going pulse of the same amplitude and duration. At a period of between 100–120*s* after the occurrence of the negative-going pulse, a further pair of successive positive-going and negative-going pulses is generated. The positive-going pulses are labelled 'set' pulses while the negative-going pulses are labelled ' reset' pulses.

The reason for choosing set and reset pulses of opposite polarity is to avoid ambiguity in question of solenoid 58 when the circuit is first energised. If the circuit were previously deenergized while in the resting state, and if the first pulse received when next energized is a negative-going pulse, the solenoid 58 is not operated, and so the circuit is kept static until arrival of the next

positive pulse. Thus the risk is avoided of having the boots inflated during the long resting phase, and kept deflated during the intended inflation phase, as could happen were both the set and reset pulses were of the same polarity.

As already mentioned, these pulses are applied to the respective terminals of solenoid **58**, the setting pulses serving to switch the valve **6** into the position in which the source **2** applies a continuous stream of gas under pressure to device **12** through pressure regulator **8**. When a reset pulse is received, the valve is returned to the illustrated position in which no further pressurised gas is supplied to regulator **8**, the conduit upstream thereof being vented to atmosphere.

The function of capacitor C is to act as an energy-storing device to ensure that the current drain on battery **54** is reduced to the minimum constant with reliable operation, while at the same time lengthening the life of battery **54** so that it needs to be replaced only at infrequent intervals. The timing circuit **56** is such that when a set or reset pulse is applied by it to solenoid **58**, most of the energy for the pulse is derived from capacitor C. Thus ensures that the capacitor C is charged by battery **54** when no pulses are being produced by the timer, thus converting a substantially constant current drain on battery **54** into intermittent current pulses of relatively high amplitude. The function of pressure switch **52** is to disconnect the battery **54**, and disable the timer circuit, when there is insufficient gas pressure in the inlet to the pneumatic circuit to operate the pneumatic boots **38**.

The boots **38** themselves are already known, and so will not be described in great detail in this specification. The boots are double-walled, and at least the inner wall is made of a flexible plastics material which is able to take up the contours of the patient's lower leg and foot. Air under pressure is introduced into the space between the two walls. When the air of other gas is first introduced, it causes the outer wall to distend until it reaches its final shape, after which the further increase in pressure forces the inner wall more and more firmly against the patient's limb. This pressure is transmitted to the patient's veins and other blood vessels, causing them to dilate.

This contraction expels blood from the vessels in the direction dictated by the usual valving arrangements forming part of the body's vascular system. When a desired maximum pressure has been reached the pneumatic pressure in the boot is released, as by venting to atmosphere the space between the two walls of the boot. This reduction in pressure allows fresh blood to be pumped by the heart into the limbs and blood vessels. The cyclic compression and expansion applied by the boots simulates the 'massaging' of the legs' blood vessels which is normally applied by the calf muscles when the patient is standing or walking, but which action is inhibited or stopped when the patient is anaesthetized and is in a lying position.

The present invention therefore increases both the peak femoral vein flow and pulsatility, leading to the same mean mass transfer of blood as when the body is working normally.

In accordance with the present invention, it has been found that the effectiveness of the pneumatic boots is related closely to the pattern of the pressure cycle to which they are subjected. In particular, it has been found that amongst the critical factors are: the rate at which pressurizing gas is applied to the pneumatic boots; the maximum which this pressure reaches; the speed with which the pressure is reduced, and the timing between successive pressurization cycles. These characteristics are indicated diagrammatically in FIG. **4**. Before these are discussed in any further detail, the operation of the venous flow stimulator will be described in further detail.

In the initial, unenergized, state of the stimulator, the bellows **26** is in its deflated condition, being biased to that position by a compression spring (not shown). The detailed construction and operation of the bellows is as described in our UK patent specification No. **866 758**, and so will not be described in greater detail herein. In this position the magnet **28** is more effective than is magnet **22**, thus biasing the rocker **18** open so that the inlet **16** of conduit **34** is in communication with chamber **14**. The exhaust valve **44** is open, allowing the interior of both boots **38** to vent to atmosphere.

When it is desired to start operation of the apparatus, the gas under pressure is applied to pressure switch **52** and to valve **6** from a suitable source, such as a cylinder of compressed air, nitrogen or oxygen. The use of oxygen might seem surprising, in view of its higher cost but it has been found that oxygen is usually more readily available in hospitals than the other gases and so is more convenient to use despite its higher cost. The possible or preferred use of oxygen means that none of the valves in the apparatus, at least on the high-pressure side thereof, can be lubricated, because oxygen can react explosively with some lubricants under certain conditions. The valves are therefore designed with the use of oxygen in mind.

Closure of pressure switch **52** causes the timer **56** to send out a set pulse to solenoid **58**. This switches over valve **6** to the position in which gas under pressure flows through the pressure regulator **8** and into the interior of chamber **14**. From there, the rocker **18** being open, it passes into injector **36**, is diluted with atmospheric air and passes into the operating volume of the pneumatic boots **38**. As soon as a superatmospheric pressure is generated in conduit **34** this causes the exhaust valve **44** to be switched over so that the conduit is isolated from the atmosphere. By virtue of conduits **34** and **42**, the pressure in the interior of the boots **38** is transmitted to the pressure-relief valve **46** and to the interior of control chamber **24** of device **12**. As this pressure is greater than that needed to overcome the force of the biasing spring, the chamber **24** starts to increase in volume, although gas is bled away from chamber **24** at a rate determined by the setting of needle valve **32**. Under normal conditions of operation, the valve **32** bleeds gas away from chamber **24** at a rate much lower than that at which gas enters the chamber from conduit **42**, so that the bellows **26** are distended at a chosen rate. As the magnet **28** is moved away from rocker **18** by this distention of the bellows, there comes a point when the field of magnet **28** is less effective than that of magnet **22**, and the rocker valve closes. This is arranged to take place when the pressure in the interior of boots **38** has reached a desired maximum. According to the teaching of the present invention, a desired rate of pressurization of the boots is such that the operating pressure therein should increase at the rate of **8** mm of mercury (Hg) per second, and the desired maximum value should be of the order of **50** mm Hg, all the pressures being measured above atmo-

spheric. Thus the boots would take about 6–7 seconds to inflate.

When the rocker **18** has switched over, this causes the pressure in chamber **14** to increase until the arrival of the next reset pulse at solenoid **58**, but this pressure is not passed on the pneumatic boots, because of the closure of the rocker valve **18**. When the reset pulse does arrive, it switches over valve **6** and enables chamber **14** to be vented to atmosphere

With closure of rocker valve **18**, the reduction of pressure in conduit **34** allows valve **44** to open, thus venting to atmosphere the interior of both boots **38**. It is envisaged that this venting would take place under the natural compliance of the system but it could be assisted by a partial-vacuum device (not shown) adapted to apply a measure of vacuum to the interior of the boot to increase the rate at which they are deflated. This reduction in pressure closes the non-return valve **48**, but the chamber **24** continues to be vented through valve **32**, thus allowing magnet **28** to move towards the position in which it is effective to open rocker **28**. However, the rate-of-return of magnet **28** is governed so that by the time it is effective to open the rocker valve, the inlet valve **6** has received the reset pulse and closed.

The stimulator then stays in its rest position awaiting the arrival of the next set pulse, which occurs some **100** to **120** seconds after the preceding reset pulse. This interval is usually set by the manufacture of the stimulator, or it may be under the control of the anaesthetist or other person in the operating theatre.

It has been found that the stimulation of the blood-pumping movement of the calf muscles is so effective that the venous flow stimulator of the present invention need be used only during the surgical operation.

It is within the purview of the present invention to apply the pressure pulses to the two boots alternately. This would require a modification in the outlet circuit of the stimulator, involving principally the addition of a pneumatic flip-flop valve, and to altering the timing circuit of the stimulator so that it generates pulses of the same shape but at twice the frequency described above. This would ensure that alternate pulses would be applied to each of the boots, so that each of the boots would receive exactly the same cycle of pulses as described above, but with the two cycles being out of phase with each other. However, so far it has been found by experiments that there is no significant advantage to the patient in having alternate pressurization of the boots, and so the additional cost and complication of providing this option are not usually justified.

What we claim is:

1. An apparatus useable in conjunction with a source or pressurized gas for stimulating venous blood flow in the legs of patients undergoing surgery, said apparatus including at least one double-walled pneumatic boot positioned on and completely enclosing a patient's leg and foot; said boot having an operating space defined between the walls thereof; a supply valve operative to control the supply of gas at a suitable pressure from a pressurized source to the operating space; means responsive to the gas pressure in the operating space for closing the supply valve when the pressure reaches a chosen maximum valve; a timer means adapted to produce a series of successive set and reset pulses, and an inlet valve means, controlled by the timer, for supplying gas to the supply valve upon receipt of a set pulse, and for discontinuing the supply of gas upon receipt of a reset pulse.

2. A venous flow stimulator as claimed in claim **1**, including injector means positioned downstream of the supply valve between the supply valve and boot for receiving high-pressure gas from the open supply valve and for diluting it with atmospheric air thereby producing a larger volume of gas at lower pressure for feeding to the pneumatic boot as long as the supply valve is open.

3. A venous flow stimulator as claimed in claim **1**, including means for energizing the timer only when the pressure of the supply of gas to the said inlet valve is above a chosen minimum.

4. A venous flow stimulator as claimed in claim **3**, in which the timer is electronic and is composed of units of integrated circuitry.

5. A venous flow stimulator as claimed in claim **1**, in which the said supply valve includes a magnetic rocker valve and two permanent magnets mounted for relative movement, said rocker valve being operated by relative movement of said magnets.

6. A venous flow stimulator as claimed in claim **5**, in which the said supply valve includes a bellows having a portion thereof movable relative to said rocker valve, said movable portion carrying one of the said two permanent magnets for movement thereof toward and away from actuating relationship with the rocker valve.

7. A venous flow stimulator as claimed in claim **6**, including an adjustable bleed valve in the bellows, said bleed valve venting the bellows to atmosphere at a desired rate.

8. A venous flow stimulator as claimed in claim **1**, including an exhaust valve biased to the open position, said exhaust valve being operatively controlled by the outlet pressure of the gas from the supply valve in a manner whereby when the outlet pressure exceeds a chosen valve the exhaust will close, the inlet of the exhaust valve being in communication with the operating space of the boot for a selective venting thereof.

9. A venous flow stimulator as claimed in claim **4**, in which the timer produces set and reset pulses of opposite polarity.

10. A venous flow stimulator as claimed in claim **9**, in which the intervals between successive set and reset pulses is approximately **10** seconds, and between successive reset and set pulses is approximately **100** – 120 seconds.

11. A venous flow stimulator as claimed in claim **10**, in which shunted across input terminals of the timer is a capacitor adapted to be discharged through the timer to contribute energy to the pulses, and to be charged in the intervals between the pulses.

12. The method of stimulating venous blood flow in the leg of a patient undergoing surgery comprising intermittently forcing blood from the veins of the leg by an intermittent pressurization of a leg and foot encasing pneumatic boot at an increasing rate of **8** mm of mercury per second to a maximum on the order of **50** mm of mercury, and subsequently releasing the pressure.

* * * * *

United States Patent [19]

Christoffel

[11] **4,186,732**

[45] **Feb. 5, 1980**

[54] **METHOD AND APPARATUS FOR PULSING A BLOOD FLOW STIMULATOR**

[75] Inventor: **William D. Christoffel**, Two Rivers, Wis.

[73] Assignee: **American Hospital Supply Corporation**, Evanston, Ill.

[21] Appl. No.: **857,312**

[22] Filed: **Dec. 5, 1977**

[51] **Int. Cl.**[2] **A61H 1/00**

[52] **U.S. Cl.** ..... **128/24 R**

[58] **Field of Search** ..... 128/2.05 M, 24 R, 28, 128/30, 30.2, 64, 297, 298, 299, DIG. 10, DIG. 20, 327; 137/87, 624.11-624.16

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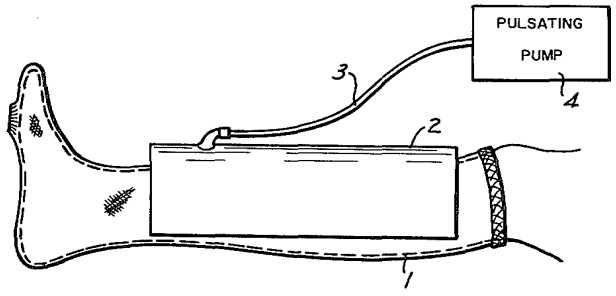
Primary Examiner—Richard J. Apley
Attorney, Agent, or Firm—Larry N. Barger

[57] **ABSTRACT**

A method and apparatus for sequentially inflating and deflating a compression device or the like to stimulate blood flow and prevent deep vein thrombosis. The apparatus includes an air compressor with a regulator valve providing fast inflation of such device to a pressure of approximately 60 mm Hg (1.2 psi) within 3 to 7 seconds. A pulse timer and a delay timer in the system are coupled together for actuating the compressor and a pressure relief valve to peak and maintain a pressure in the device for a measured period of time.

20 Claims, 4 Drawing Figures



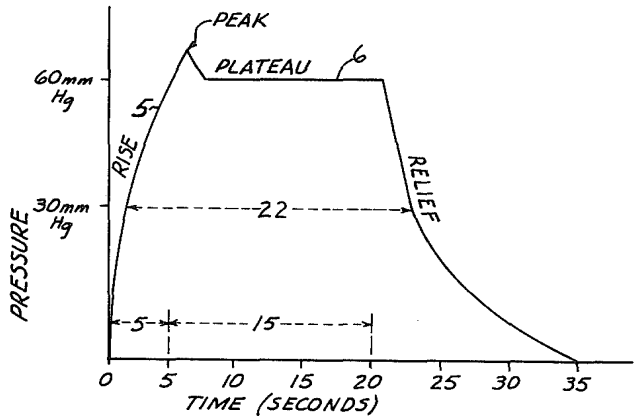
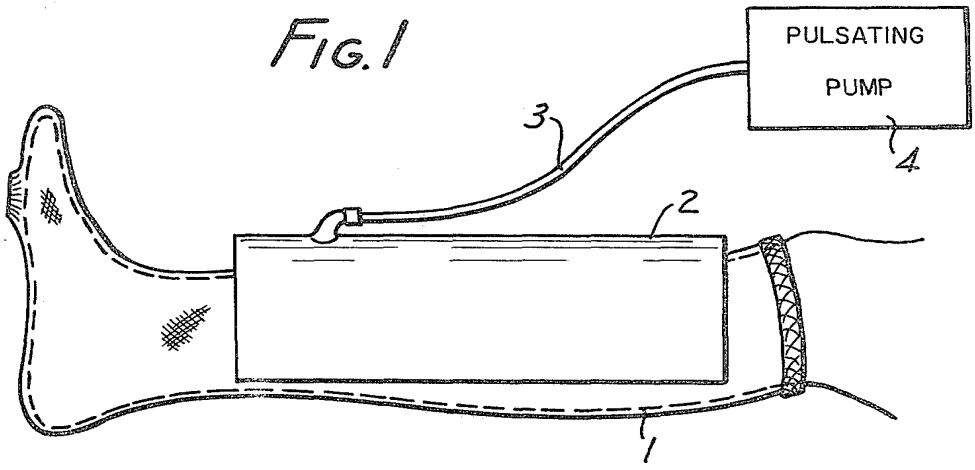


FIG. 1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3
4
2
1

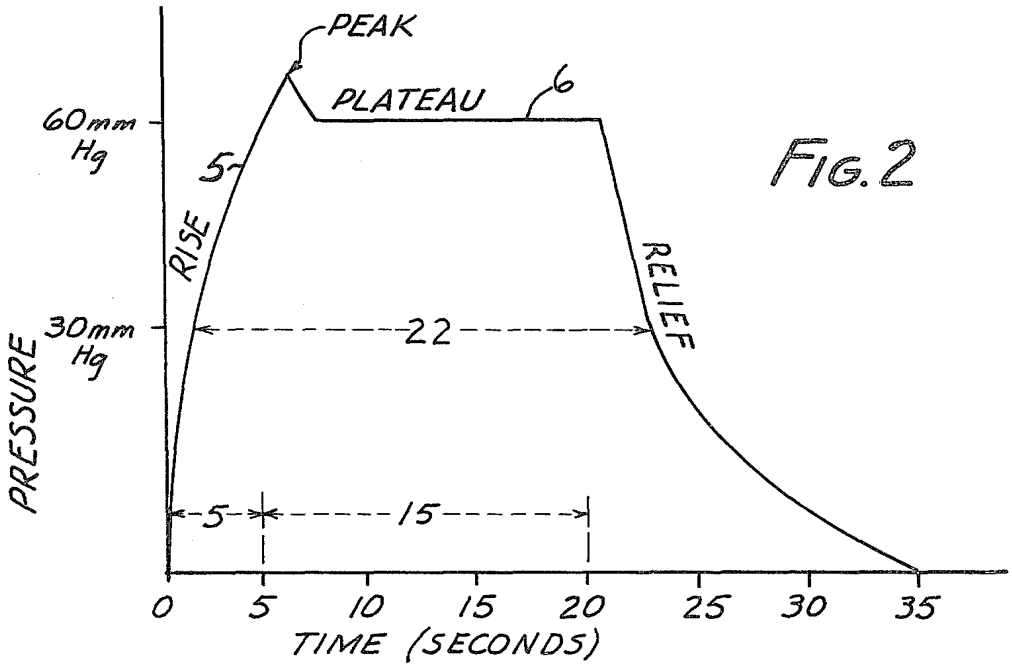

PEAK
PLATEAU
6
60mm Hg
5
RISE
30mm Hg
PRESSURE
22
RELIEF
5
15
0
5
10
15
20
25
30
35
TIME (SECONDS)

FIG. 2

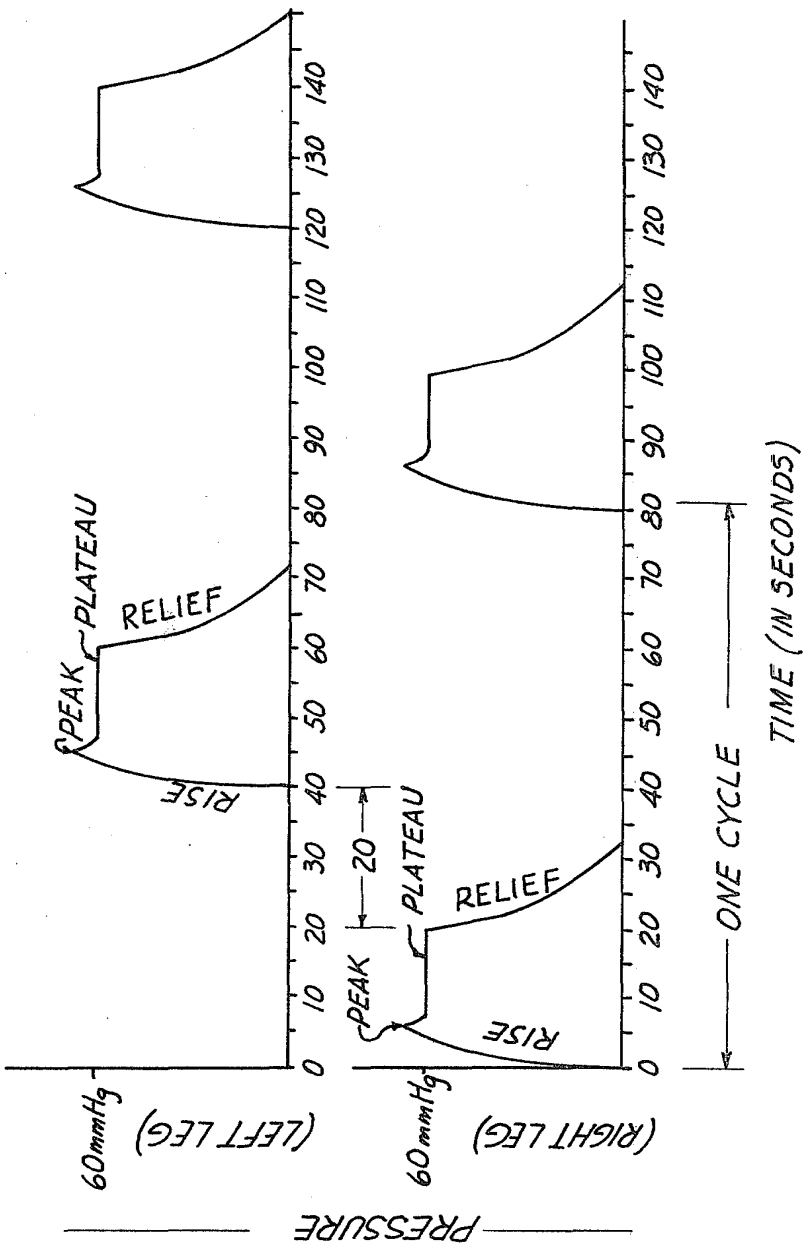

PRESSURE
60 mmHg
(LEFT LEG)
PEAK
PLATEAU
RELIEF
RISE
20
60 mmHg
(RIGHT LEG)
PEAK
PLATEAU
RELIEF
RISE
ONE CYCLE
TIME (IN SECONDS)
0
10
20
30
40
50
60
70
80
90
100
110
120
130
140

FIG. 3

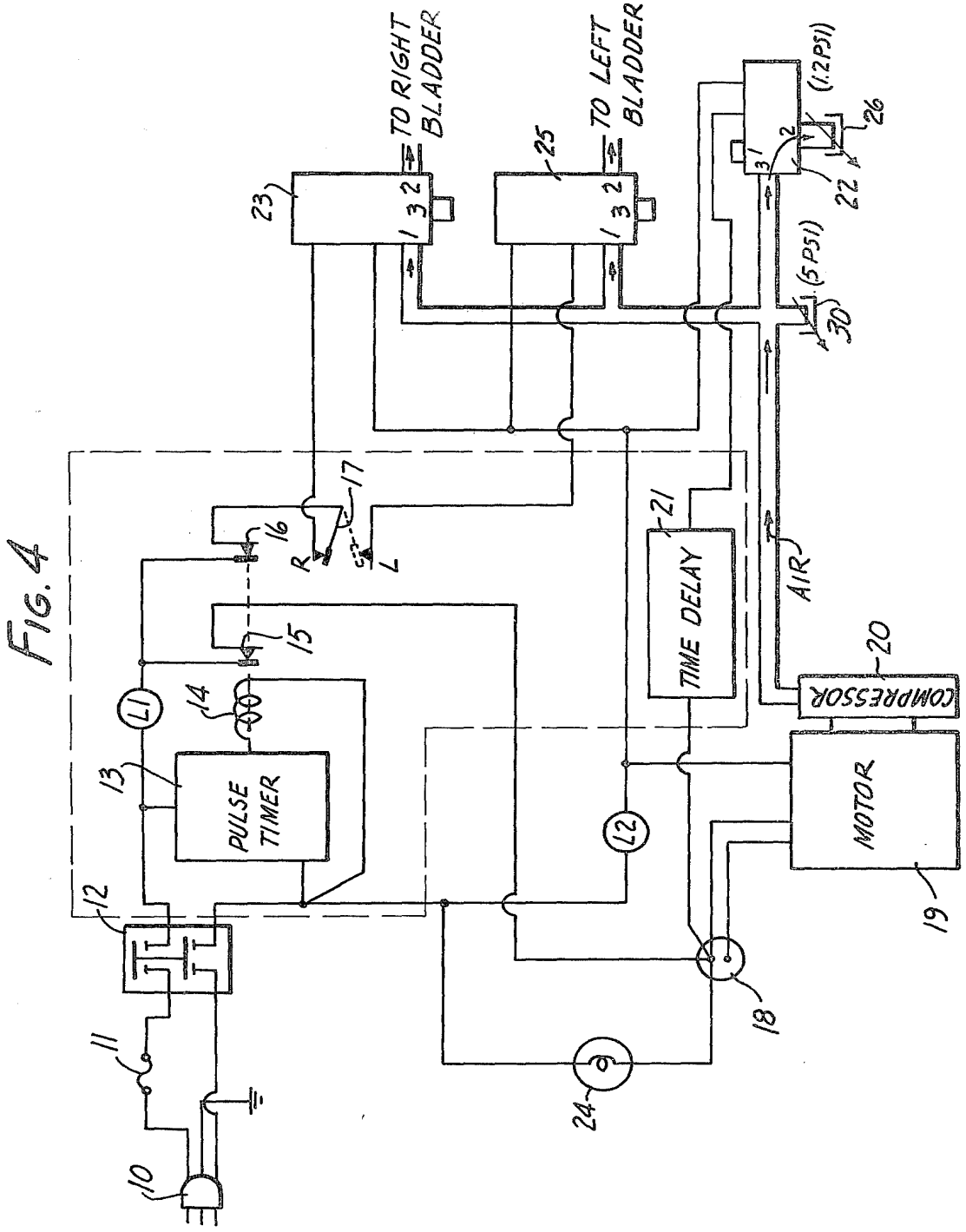

TO RIGHT BLADDER
TO LEFT BLADDER
(1.2 PSI)
(5 PSI)
AIR
TIME DELAY
COMPRESSOR
MOTOR
PULSE TIMER
L1
L2
R
L
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
30

FIG. 4

METHOD AND APPARATUS FOR PULSING A BLOOD FLOW STIMULATOR

BACKGROUND OF THE INVENTION

There have been various body compressing devices proposed to sequentially squeeze a patient's limbs, usually the legs, to aid in blood circulation. Such compression devices are intended to prevent pooling of blood in limb extremities where a deep vein thrombosis (blood clot) can form.

One type of patient limb compression device is described in a co-pending application by Bishop and Choksi, entitled Pulsatile Stocking and Bladder Therefor, Ser. No. 820,104, filed July 29, 1977, now U.S. Pat. No. 4,153,050. The subject matter of the present application deals with an improved pumping system for sequentially inflating a limb compressing device, such as the stocking described in the above co-pending application.

It has been known to use air compressors, and tanks of compressed air to inflate body compressing devices, which were thereafter deflated by venting a valve to the atmosphere. Examples of such inflation systems are described in U.S. Pat. Nos. 2,140,898; 2,145,932; 2,674,231; 3,901,221; and 3,942,518. The inflation systems described in this prior art would either provide a very slow rise time to the desired pressure, or include large cumbersome compressed air tanks or compressors that are not easily portable throughout the hospital. It is noted that the compact air supply unit described in the present application may be conveniently disconnected from the stocking described in the above copending Bishop and Choksi application. The stocking/bladder device is lightweight and pliable permitting ambulatory patients to walk while still wearing such stockings.

It has also been determined that blood circulation is improved if the compression device is quickly inflated to a slight pressure peak, 5 to 10 mm Hg above its desired plateau pressure, and held at a generally constant plateau pressure for more than 10 seconds, and then deflated. The prior inflation systems for limb compressing devices inflated them in either one or two steps to a peak pressure point and immediately deflated the device. With such arrangement, much of the blood flow stimulation occurs at less than peak pressure. It is believed that a greater volume of blood can be pumped through the limb with a compression cycle that has a generally constant plateau pressure for a considerable period of time.

SUMMARY OF THE INVENTION

The present invention provides an improved inflation system for a limb compressing device that can provide a fast rise time of 50 to 70 mm Hg (1 to 1.4 psi) in a period of 3–7 seconds, and thereafter maintain a generally constant plateau pressure at this level for at least 10 seconds. The system has a small portable air compressor, weighing approximately 9 pounds, with an output pressure of greater than 520 mm Hg (10 psi). A regulator off the compressor establishes an intermediate supply pressure in the range of 110 to 520 mm Hg (2 to 10 psi) for inflating the device to a pressure peak and plateau pressure below 110 mm Hg (2 psi). After the quick rise time, the generally constant plateau pressure is maintained by a pressure relief valve that permits excess air to escape from the compressor.

At the end of the pressure cycle, a portion of the air is forced out of the device through the connecting tubing and out of the exhaust port of the 3-way valve. The air evacuates due to the force created as the patient's leg expands back to its normal size, due to elasticity of the stocking and due to atmospheric pressure. Air in the device remains at atmospheric pressure until the next pressure cycle. Actuation of the above cycle is controlled by a pulse timer and a delay timer coupled together for operating the compressor, two 3-way valves and a rise time valve provided with a preset pressure relief valve set at the desired plateau pressure. The pulse timer actuates a flip-flop relay to alternate the pressure cycle to either the right or left leg.

THE DRAWINGS

FIG. 1 is a side elevational view of a patient limb compression device that is inflated and deflated by the system of this invention;

FIG. 2 is a graph showing the preferred fast rise time, generally constant plateau pressure and decompression of the device;

FIG. 3 is a graph showing the sequence of pulse cycles between devices on both legs of a patient; and

FIG. 4 is a schematic view of the electrical and air circuits of the inflation system.

DETAILED DESCRIPTION

FIG. 1 shows a schematic view of a limb compression device 1, such as a stocking, that has a bladder chamber 2 into which fits an inflatable bladder (not shown). A tube 3 connects a bladder within chamber 2 to a pulsing pump device 4. The stocking and bladder form no part of this invention and are shown only for background information. This invention relates to the pulsating pump device 4 and to its structure and method of inflating the patient compression device.

The pumping device 4 is a small portable unit weighing only approximately 16 pounds. To provide a very quick and reliable rise time in inflating the bladder, the compressor has an output of more than 520 mm Hg (10 psi). An output of 780 mm Hg (15 psi) works very well, but the output pressure could be 1040 mm Hg (20 psi), if desired. The compressor provides air to the system controlled by a pressure regulator 30 (FIG. 4), to provide an intermediate control pressure of approximately 260 mm Hg (5 psi). Depending on the rise time and plateau pressure desired, this intermediate control pressure could be within the range of 140 mm Hg (2 psi) to 520 mm Hg (10 psi).

An air compressor that merely puts out 260 mm Hg (5 psi) could be more likely to vary in its output pressure under differing loads on the motor during start up, etc. This could change the inflation pressure at the 5 second delay time. A compressor has been previously tried which put out 260 mm Hg (5 psi), but it was unsuccessful because of the inordinately long period of time it took to inflate the bladder. It might be possible that a compressor putting out 260 mm Hg (5 psi) which included a very large compressed air storage tank, such as used in gasoline stations to inflate tires, might provide the proper inflation time because of the large backup air supply reservoir. However, such large and cumbersome compressor would not be practical for portable hospital use. The compressor described in the present application is preferably used without a storage tank to reduce costs and weight. In applicant's device compressed air from the 260 mm Hg (5 psi) regulator valve 30 (FIG. 4)

valve is supplied directly to the compression stocking to inflate its bladder to approximately 60 mm Hg (1.2 psi) in the preferred 5 second time. There is no storage tank.

As shown in FIG. 2, the fast rise portion is shown as numeral 5 on the graph. The pressure reaches a peak, preferably in the range of 5 to 10 mm Hg above the plateau pressure of 50 to 70 mm Hg, in a period of 3 to 7 seconds. The pressure increase is then halted with a timing means to establish a generally constant plateau pressure for at least 10 seconds (shown in FIG. 2 as approximately 14 seconds). In FIG. 2, this plateau pressure is illustrated as 60 mm Hg, and after approximately 14 seconds, a timing means actuates the deflation of the bladder.

From FIG. 2 it can be seen that the pressure is maintained above 30 mm Hg (0.6 psi) for a considerably long time, i.e. 20 seconds, but could be in the range of 15 to 25 seconds. The plateau pressure, approximately 60 mm Hg (1.2 psi), is maintained for at least 10 seconds at a generally constant pressure. While it is recognized there might be slight fluctuations in the plateau pressure, such fluctuations would be within a pressure range of 8 mm Hg or less.

The pressure versus time graph of FIG. 2 shows only the sequence of the inflation, pressure peak, plateau, and relief (deflation). FIG. 3 shows how these sequences are combined for alternating pulses between the patient's left and right legs which both have compression devices, such as shown in FIG. 1. For each leg, the cycle is approximately 80 seconds long and thereafter repeats itself. It is noted in FIG. 3 that the rise time plus the peak and plateau time for one leg is 20 seconds, while the time between terminating the plateau pressure of that particular leg and start of the rise time of the opposite leg is also 20 seconds. Therefore, a simple alternating or pulse timer, as will be explained later, can control a compressor output with a repeating timing sequence of 20 seconds "on" and 20 seconds "off". For purposes of this application, the rise time is defined as the time to reach the peak pressure. It is understood that the peak pressure is shown schematically and in practice may have a more tapered blending with the plateau pressure.

Still referring to FIGS. 2 and 3, the sharp rise time of approximately 5 seconds to approximately 70 mm Hg (1.4 psi) is controlled by a 5 second delay timer. The tolerance on such timer is between 4.5 and 5.5 seconds. In FIG. 2 as the compressor starts to inflate the bladder of the compression device, the delay timer kicks in after 5 seconds and opens a valve that is set at 60 mm Hg (1.2 psi). This causes the pressure rise to stop and establish a generally constant plateau pressure for a period of 10 seconds or more. It has been found that the peak and the plateau pressures are more easily controllable by measuring the time rather than the pressure. Because of a controlled intermediate pressure from regulator 30 supplying the stocking bladder, a given period of time, i.e. 5 seconds, will establish the desired peak and plateau pressure of approximately 70 mm Hg and 60 mm Hg respectively.

The interrelationship between the pulse timer and delay timer which are electrically coupled is best seen in FIG. 3. At time zero, the pulse timer begins its "on" cycle for 20 seconds, and at the same time the 5 second delay timer begins its count. At the end of 5 seconds, the peak pressure of approximately 65–70 mm Hg has been reached. The delay timer actuates solenoid valve 22 so that an approximately constant plateau pressure is maintained. Because the compressor is still running while air is bleeding out of the solenoid valve 22 and pressure relief valve 26, this tends to dampen out the fluctuations in the generally constant plateau pressure.

At the end of its 20 second "on" time, the pulse timer sequences to its 20 second "off" time and shuts off the compressor output. Valve 23 or 25 exhausts air through the respective valve from port 2 to port 3 during the "off" time, causing the bladders to deflate to atmospheric pressure with approximately 15 seconds. At the end of its 20 second "off" time, the pulse timer starts the compressor output and switches the inflation to the bladder of the opposite leg. Initiation of the "on" cycle also triggers the delay timer which begins its 5 second count. After the second leg bladder has been inflated and deflated, the cycle, which takes approximately 80 seconds, has been completed.

It has been found that the very fast rise time, the peak pressure, the period of pressure of above 30 mm Hg, and the generally constant plateau pressure for at least 10 seconds, provides improved blood flow stimulation. Such pressure and time profiles are generated by the interreaction of the pulse timer, the delay timer, the compressor and its pressure relief valves.

The schematic electrical and air diagrams describing the interrelationship of these parts is shown in FIG. 4. Here a grounding type plug 10 for connecting to a 120 volt, 60 Hz power supply is provided. The current L1 is routed through the cord, fuse 11, and through a lighted double pole on-off switch 12 to a pulse timer 13. The constant output pulses of the timer consist of 20 seconds "on" time followed by 20 seconds "off" time.

A first "on" pulse energizes the coil of an alternating relay 14 latching to a relay armature causing contact 15 and 16 to be made. Contact 17 has assumed the position designated as R during the previous "off" period of the timer. The two positions of contact 17 indicate right bladder and left bladder. The circuit as shown in FIG. 4 is completed to L2.

Current flows from contact 15 to the capacitor 18 of motor 19 which drives compressor 20. The circuit is also complete to the 5 second time delay relay 21 that is connected to a solenoid actuated valve 22. During this condition, the motor driven compressor operates and the solenoid operated air valve 23 controlling the right bladder opens.

Simultaneous to the above, the time delay relay 21, which is in series with the solenoid operated (normally closed) air escape valve 22 prevents the solenoid from being energized until 5 seconds have elapsed. This actions activates regulator 30, causing the right bladder to fill to the established 60 mm Hg pressure within the specified time of 5 seconds. The pressure indicator light 24 is illuminated.

After 5 seconds have elapsed, the time delay relay completes the circuit to the solenoid actuated escape valve 22 allowing air to escape at a balanced rate from pressure relief valve 26 and maintain the generally constant peak pressure.

Upon completion of the pulse timer's "on" pulse of 20 seconds, the relay coil 14 becomes deenergized, releasing the armature and interrupting contacts 15 and 16. Thus, current is interrupted to the motor driving the compressor and solenoid valves 23 or 25. Also, during the release of relay armature 14, contact 17 assumes the left leg position L.

During the ensuing 20 second "off" period of the pulse timer, air pressure in the right bladder is relieved

through the air conduit through exhaust port 3 of valve 23.

Another 20 second "on" period follows, again causing contacts 15 and 16 to be made. Contact 17 has assumed position L during the preceding "off" period of the pulse timer. The solenoid air valve 25 of the left bladder opens. The sequence of operation is as described for the previous "on" period, except that air is now directed to the left leg bladder. The indicator light 24 is illuminated. Another 20 second "off" period of the pulse timer follows, completing the total cycle time of 80 seconds. The cycle is then repeated.

It is important that there be a primary pulse timer and a secondary delay timer to perform the functions described above. If desired, these two timers could be consolidated into a single component which performs these two separate timing functions.

If desired, solenoid valves 23 and 25 could be consolidated into a single 4-way valve to reduce cost. The function of the 4-way valve would be the same as the two 3-way valves.

Various types of timers can be used for the pulse timer and the time delay relay. Examples are the solid state Schmidt trigger, R-C circuit, or a binary counter device. In FIG. 4, all the components within the dotted line could be replaced with a compact solid state timer board assembly. If desired, the solid state timer board assembly could be designed with an adjustment (to be made by qualified technical personel) to alter the peak spike pattern.

The motor, compressor, timers, solenoid valves, etc. are preferably compactly packaged in a small case for easy portability.

In the foregoing description, a specific example has been used to describe the invention. It is understood by those skilled in the art that certain modifications can be made to this example without departing from the spirit and scope of the invention.

I claim:

1. A method of controlling the inflation rate and pressure in a body compression device for aiding blood circulation comprising the steps of:

(a) utilizing a gas pressure at an output of a gas supply source that is greater than the desired operating pressure for the device;

(b) venting a portion of the gas from the output to establish a control pressure less than said gas supply pressure;

(c) dispensing gas at the control pressure into the device for a measured period of time which automatically provides a predetermined inflation rate and operating pressure; and

(d) maintaining a generally constant plateau pressure for a measured period of time by opening a balancing vent means downstream.

2. A method as set forth in claim 1, wherein the controlled gas is vented and dispensed simultaneously.

3. A method as set forth in claim 1, wherein the output pressure is above 520 mm Hg (10 psi).

4. A method as set forth in claim 1, wherein the control pressure is within the range of 50 to 520 mm Hg (1 to 10 psi).

5. A method as set forth in claim 1, wherein the device's peak pressure is below 101 mm Hg (2 psi).

6. A method as set forth in claim 1, wherein the device is inflated to a pressure above 30 mm Hg (0.6 psi) in less than 7 seconds, and maintained at or above this pressure for a period of 15 to 25 seconds.

7. A method as set forth in claim 1, wherein the device is inflated to a pressure of 50 to 70 mm Hg (1 to 1.4 psi) within a period of 3–7 seconds.

8. A method as set forth in claim 1, wherein the generally constant plateau pressure is in the range of 50 to 70 mm Hg (1 to 1.4 psi).

9. A method as set forth in claim 8, wherein the generally constant plateau pressure is maintained for a period greater than 10 seconds.

10. A method as set forth in claim 1, wherein the device is deflated by actuating a control valve that exhausts air to the atmosphere.

11. A method as set forth in claim 1, wherein the method includes applying pulses alternately to a plurality of limb compression devices.

12. A method as set forth in claim 1, wherein the gas supply source is an air compressor with a motor; and the motor is on for a period of 15 to 25 seconds during compression, and is shut off for a subsequent period of 15 to 25 seconds in a repeating cycle.

13. Apparatus for supplying intermittent pressure to a body compression device for aiding in blood circulation comprising: a gas pressure source capable of generating gas pressures sufficiently high to inflate such device to a pressure of 50 to 70 mm Hg (1 to 1.4 psi) within 3 to 7 seconds; a first timer for alternately starting and stopping gas flow from the source to the device; a second timer coupled to the first timer for actuating means to limit peak pressure in the device; and said apparatus has a downstream balancing vent means operably connected to said timers for maintaining such device in inflated condition at a generally constant plateau pressure which varies less than 8 mm Hg for a period greater than 10 seconds.

14. Apparatus as set forth in claim 13, wherein the first timer is a pulse timer with a preset "off" time of 15–25 seconds alternately with a preset "on" time of 15–25 seconds.

15. Apparatus as set forth in claim 13, wherein the second timer is a delay timer preset to begin a delay count at the initiation of an "on" period of the first timer.

16. Apparatus for supplying intermittent pressure to a body compression device for aiding in blood circulation comprising: an air compressor capable of generating air pressure sufficiently high to inflate the device to above 30 mm Hg in less than 7 seconds; a downstream balancing vent valve having a relief pressure and flow capacity balanced against the air being supplied to such device to maintain a generally constant plateau pressure in the device for a period of time while the compressor is running; and timing means on the apparatus for signaling the opening and closing of such balancing vent valve.

17. Apparatus as set forth in claim 16, wherein the balance occurs at a pressure in the range of 50 to 70 mm Hg.

18. Apparatus for supplying intermittent pressure to a body compression device for aiding in blood circulation comprising: an air compressor capable of generating air pressure substantially greater than the desired peak pressure for such device; said apparatus including timing means coupled to a downstream balancing vent means having a flow capacity and pressure balanced against the air being supplied to the device, whereby a generally constant plateau pressure is maintained by the balanced vent valve while the compressor is simultaneously delivering compressed air to the device.

19. Apparatus for supplying intermittent pressure to a body compression device for aiding blood circulation comprising: an air compressor; a downstream balancing vent valve connected between the compressor and device; and timing means to actuate the balancing vent valve and also air flow from the compressor to provide a generally constant plateau pressure that varies less than 8 mm Hg for a period of more than 10 seconds.

20. Apparatus as set forth in claim 19, wherein the timing means, compressor, and balancing vent valve establish a peak pressure in the range of 50 to 70 mm Hg (1 to 1.4 psi) within approximately 5 seconds.

* * * * *

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 48577.2.1

Filtvedt, et al.

Application No.: 10/749,150 Examiner: Huong Q. Pham

Filed: December 30, 2003 Group Art Unit: 3743

For: DEVICE FOR APPLYING A PULSATING PRESSURE TO A LOCAL REGION OF THE BODY AND THE APPLICATIONS THEREOF

RULE 1.132 AFFIDAVIT OF ERLING BEKKESTAD REIN

Erling Bekkestad Rein, being first duly sworn, deposes and says:

A. Background

I am Erling Bekkestad Rein. I am a licensed medical doctor in Norway. To earn my licensure, I completed six years of medical school at the University of Oslo and two years of hospital internship. While in medical school, I received a scholarship from the Norwegian Army to conduct research on cardiovascular physiology in the Department of Physiology at the Institute of Basic Medical Sciences. Before medical school, I was a medical officer in the Norwegian Army, having graduated from the Norwegian Military Academy.

Currently, I am pursuing my Ph.D. at the University of Oslo. My thesis is on blood circulation and mechanisms in temperature regulation. The main method in my work is ultrasound Doppler. Our research group uses modern, non-invasive methods combined with advanced data processing techniques in our research. We have focused particularly on the rapid responses of the human cardiovascular system to different stimuli and the control mechanisms underlying these responses. At present, the group is working on the skin circulation and temperature regulation, short-term control of the central circulation and blood pressure, and muscle blood flow.

B. Purpose

I am submitting this Affidavit to explain the significance of applying pulses of negative pressure to a local region of a body at the claimed intervals.

C. The Claimed Intervals

The pending claims recite different combinations of intervals. In many claims, negative pressure is generated for between 1 and 20 seconds and released for between 2 and 15 seconds. Some claims require a smaller range of time for pressure generation, such as between 5 and 15 seconds or for 10 seconds. Likewise, some claims require a smaller range of time for pressure release, such as between 5 and 10 seconds or for 7 seconds.

D. Comparison of the Claimed Intervals to Those of the Cited References

Applying pulses of negative pressure to a local region of a body at the claimed intervals is novel over the cited references. Pulses of negative pressure cause blood vessels to dilate, thereby providing for increased blood velocity through those blood vessels. Pulses at the claimed intervals cause optimum blood velocity increases over an extended period of time. The following table highlights the relevant pulse intervals from the cited references, with the first column listing the cited reference and the second column providing the negative pressure pulse interval disclosed in that reference:

Cited Reference	Disclosed Negative Pressure Pulse Interval
MacLeod (3,292,613)	Pressure generation and pressure release occur for each heartbeat (i.e., approximately every second) (column 5, lines 9-20)
MacLeod (3,094,983)	Pressure generation and pressure release occur for each heartbeat (i.e., approximately every second) (column 1, lines 31-33)
Norton et al (3,878,839)	Pressure generation and pressure release occur for each heartbeat (i.e., approximately every second) (column 9, line 63 through column 10, line 13)
Grahn (5,683,438)	Pressure generation and pressure release occur

	for each heartbeat (i.e., approximately every second) (column 5, lines 33-34)
McGrath (3,896,794)	Not applicable because pressure pulses are positive (column 4, line 63 through column 5, line 2)
Christoffel (4,186,732)	Not applicable because pressure pulses are positive (column 1, lines 54-68)

Thus, as is shown, the claimed negative pressure pulse intervals referenced in Section C are not disclosed or taught in any of the cited references.

E. Impact of the Claimed Negative Pressure Pulse Intervals on Blood Velocity

Applying pulses of negative pressure to a local region of a body at the claimed intervals produces remarkable increases in blood velocity within that region. This is shown by an experiment conducted by my co-inventors and me in accordance with the invention disclosed in the present application. The following sections explain the experiment, provide the resulting data, and analyze that data. The results show that applying pulses of negative pressure at the claimed intervals has a remarkable impact on blood velocity, while doing so at other intervals does not.

1. The Experiment

Seven patients each placed his/her right arm inside a pressure tube as is shown in Figure 1.

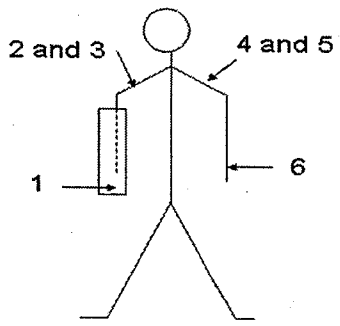


Figure 1

Blood velocity, blood pressure, and tube pressure measurements were recorded with a pulsed ultrasound Doppler machine. Blood velocity measurements were taken in arteries located at 2 and 3 for the right arm ("tube-arm") and at 4 and 5 for the left arm ("control-arm"). These arteries supply blood to the skin of the lower arms. In addition, blood pressure measurements were taken at location 6, and tube pressure measurements were taken at location 1.

2. The Resulting Data

Figure 2, which includes five plots, shows recordings for one representative patient:

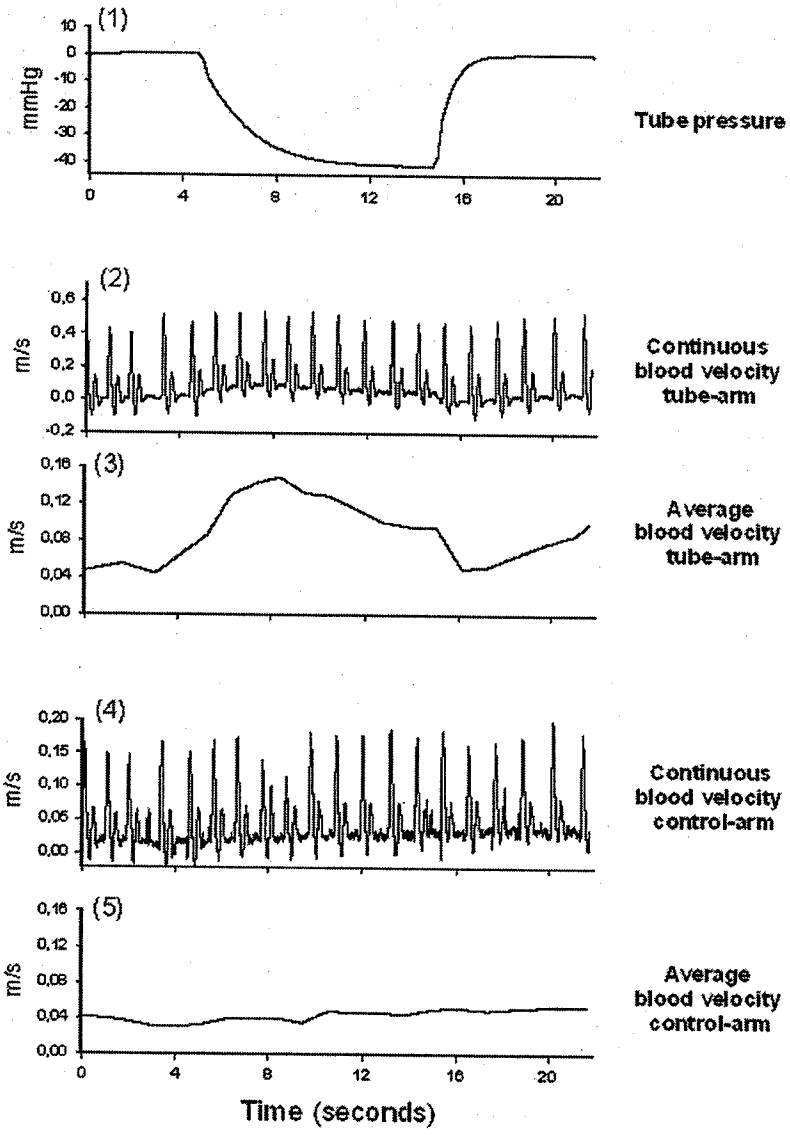


Figure 2

- Plot 1 shows a recording of one negative pressure pulse applied to the tube. The negative pressure pulse falls within the claimed intervals, as negative pressure is generated for 10 seconds (seconds 5-14) and released for 7 seconds (seconds 15-21).
- Plot 2 shows the blood velocity of the tube-arm taken on a continuous basis.
- Plot 3 shows the average blood velocity of the tube-arm calculated every second.
- Plot 4 shows the blood velocity of the control-arm taken on a continuous basis.
- Plot 5 shows the average blood velocity of the control-arm calculated every second.

Figure 3A shows average recordings for all seven of the patients when subjected to three types of negative pressure: (1) no negative pressure, (2) constant negative pressure, and (3) pulses of negative pressure falling within the scope of the present application's pending claims:

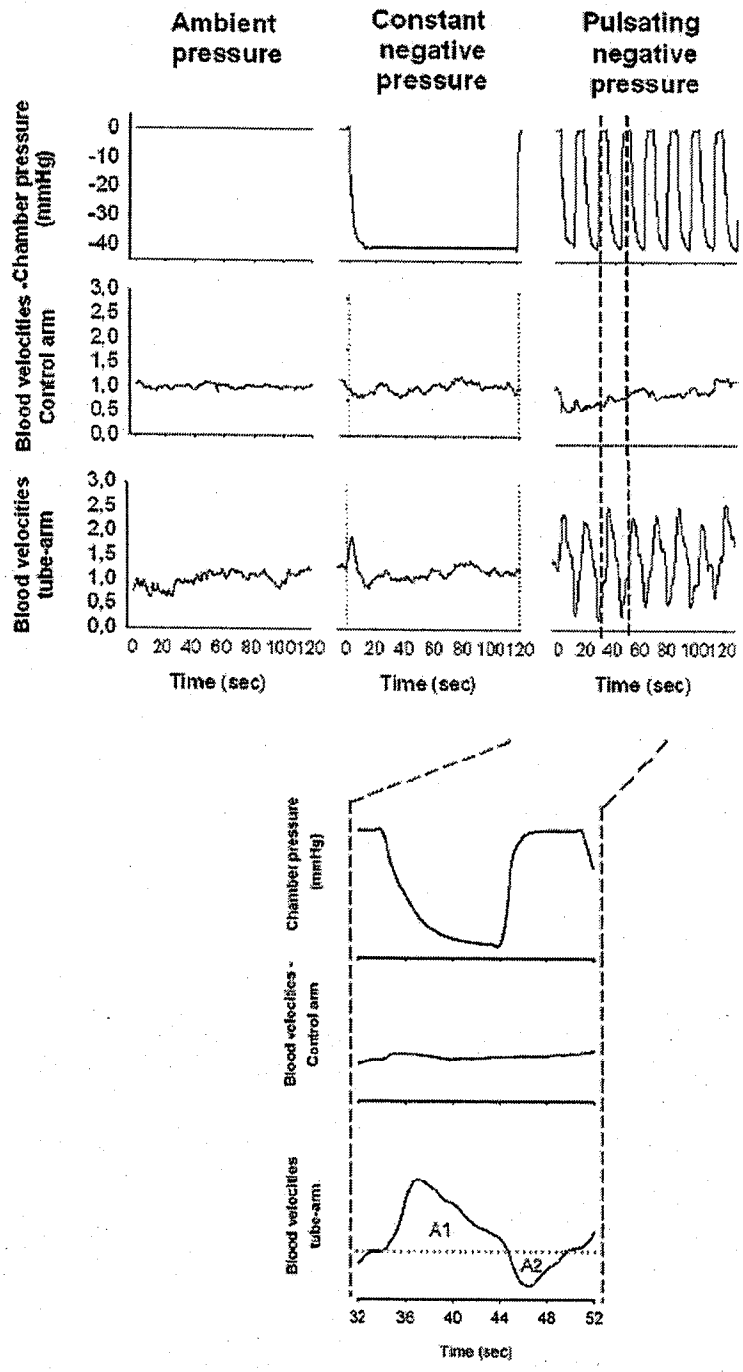


Figure 3A

For each type of pressure, measurements were taken of the tube pressure, the control-arm average blood velocity, and the tube-arm average blood velocity. The blood velocities are shown in comparison to a baseline blood velocity designated 1.0. As can be seen, the lower portion of Figure 3A magnifies a period of time when the patients were subjected to a full pulse of negative pressure falling within the scope of the present application's pending claims.

Figure 3B provides a magnified view of two important average recordings of Figure 3A:

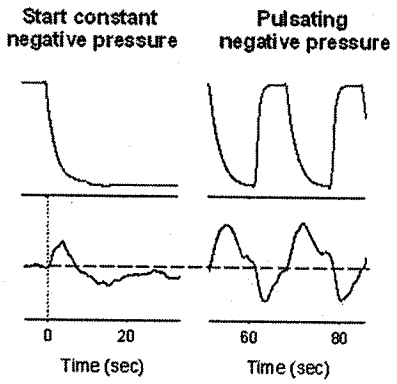
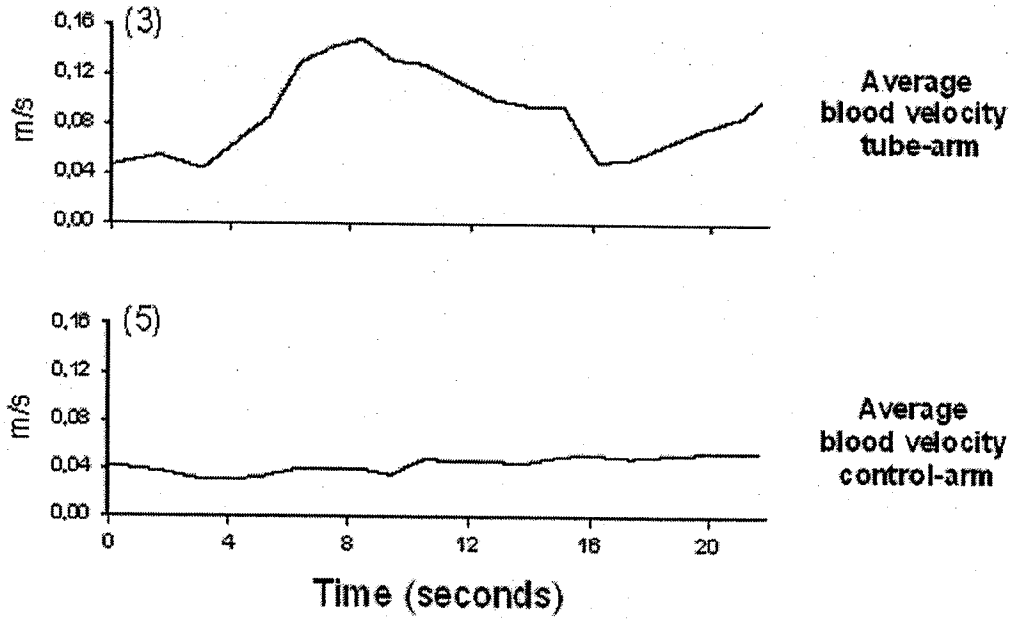


Figure 3B

The left column shows tube pressure and tube-arm average blood velocity when exposed to constant negative pressure. The right column shows those same measurements when exposed to pulses of negative pressure falling within the scope of the present application's pending claims.

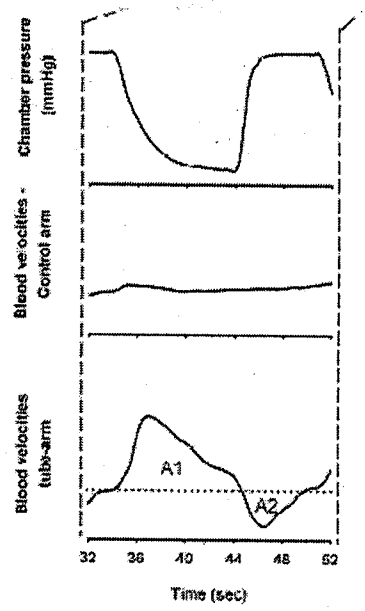
3. Analysis

The results of our experiment show that when applying pulses of negative pressure, doing so at the claimed intervals has a remarkable impact on blood velocity while doing so at other intervals has no appreciable impact. Comparing plot 3 with plot 5 of Figure 2 demonstrates the remarkable impact that the present invention has on blood velocities.



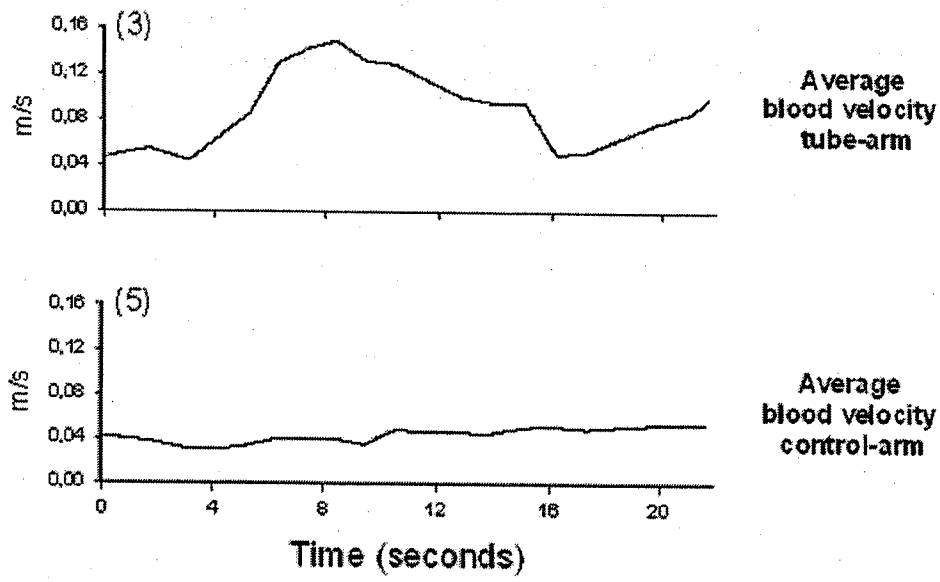
As can be seen, while the control-arm's average blood velocity hovers around 0.04 m/s, the tube-arm's average velocity increases to nearly 0.16 m/s—a nearly 400% increase! Moreover, the tube-arm's average blood velocity remains greater than that of the control-arm for the entire duration of pressure generation, as opposed to spiking up to a maximum level and quickly returning to normal.

The longer-term benefits are confirmed by viewing the lower portion of Figure 3A:



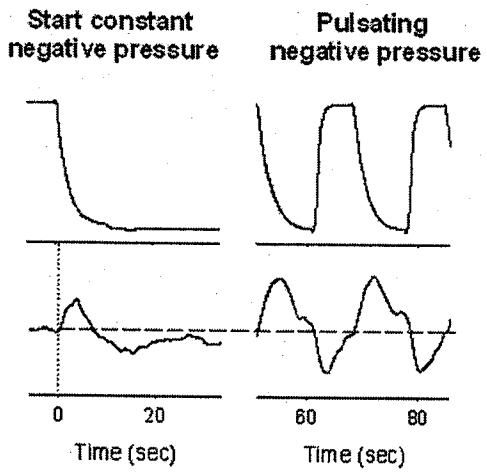
As can be seen, average blood velocity in the tube-arm is increased during pressure generation (A1) and decreased during pressure release (A2). But, as can also be seen, A1 is substantially greater than A2, meaning that the net impact of one pressure pulse is a substantial increase in average blood velocity. In fact, we have estimated the net increase in blood velocity to be greater than 50%.

In contrast, plot 3 of Figure 2 illustrates how applying a negative pressure for too short a duration misses the benefits associated with the present invention.



Under the conditions of our experiment, the average blood velocity in the tube-arm increased sharply during the first 4 seconds of negative pressure and remained higher than that of the control-arm for the next 6 seconds. During this period, the heart contracted 4-6 times. These numbers will vary under other conditions disclosed in the present application. Removing the negative pressure too soon does not allow blood velocity to build up to the point where benefits are realized. The blood vessels do not have time to adjust to the change in pressure. Accordingly, negative pressure must be applied for at least a full second in order to reap the benefits associated with the present invention.

Likewise, Figure 3B illustrates how applying negative pressure for too long a duration misses the benefits associated with the present invention:



Under the conditions of our experiment, after negative pressure has been applied for roughly 10 seconds, the average blood velocity falls below the baseline, indicating decreased blood velocity. The average blood velocity then remains lower than the baseline until the pressure is released. These numbers will vary under other conditions disclosed in the present application. The reason for this decrease is that continuous negative pressure triggers a reflex that causes the arterioles to constrict, thereby significantly decreasing blood velocity. Accordingly, negative pressure should not be applied for more than 20 seconds in order to reap the benefits associated with the present invention.

F. Article Published in the British Journal of Anaesthesia

Attached as Exhibit 1 to this Affidavit is a true and correct copy of an article published in the British Journal of Anaesthesia on January 26, 2007. The article is titled "Hypothermia During Laparotomy Can Be Prevented by Locally Applied Warm Water and Pulsating Negative Pressure." I am the first author listed in the article. This article discusses further experiments that confirm that applying negative pressure pulses to a local region of a body produces remarkable increases in blood velocity in that region.

G. Contract with the U.S. Navy

In November of 2006, my company, Thermonor AS, entered into a contract with the U.S. Navy under which we will deliver five commercial embodiments of the present invention to the

U.S. Navy for evaluation. In exchange, we will receive $500,000. The United States Congress appropriated the funding in the 2007 Defense Appropriations Bill.

H. Conclusion

For the reasons set forth above, applying pulses of pressure to a local region of a body at the claimed intervals distinguishes the pending claims over the cited references and produces remarkable increases in blood velocity in the relevant local region.

Erling Bekkestad Rein

Erling Bekkestad Rein

STATEMENT BY WITNESS FOR ERLING BEKKESTAD REIN

I, METTE HAMMERSLAND MJELDE whose full post office address is HAGA, 5650 TYSSE, NORWAY was personally present and did see Erling Bekkestad Rein, who is known to me, execute the above affidavit.

Mette H. Mjelde

(Signature of Witness)

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EXHIBIT 1

E . Advance Access published January . , 2007

British Journal of Anaesthesia Page 1 of 6
doi:10.1093/bja/ael369

BJA

Hypothermia during laparotomy can be prevented by locally applied warm water and pulsating negative pressure

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Background. Conflicting results have been obtained when using heat and constant negative pressure applied to the arm to induce re-warming in patients with mild hypothermia due to surgery. We hypothesized that pulsating negative pressure would increase skin blood flow and thus heat transfer. The purpose of this study was to compare a new method of applying heat and pulsating negative pressure to the skin with conventional forced-air warming for preventing perioperative hypothermia.

Methods. Twenty patients undergoing prolonged laparotomy for gastric surgery were randomized into two groups. One group (SM) received hospital standard method: forced-air warming, 43°C (Bair Hugger®) on the thoracic and upper arm surface. The other group (NM) received the new method: warm water and pulsating negative pressure treatment applied in a transparent acrylic cylinder (50×16 cm) on one arm. The cylinder was circulated with water at 42.5°C, leaving an air pocket inside the device. Pulsating pressure between 0 and −40 mm Hg was generated in the air pocket inside the cylinder.

Results. Two groups of 10 patients were studied. Warming was started shortly after induction of general anaesthesia. The two methods performed similarly during the first 60 min, with a mean 0.7° decrease in core temperature. The tympanic temperature curve in NM group then increased and returned to baseline (37°C) by 120 min. The temperature of SM group increased more slowly, reaching 36°C by 120 min ($P<0.05$).

Conclusion. Warm water and pulsating negative pressure was significantly better at treating hypothermia during laparotomy than forced-air warming.

Br J Anaesth 2007

Keywords: equipment, warming devices; hypothermia; surgery, laparotomy; temperature, body

Accepted for publication: November 1, 2006

Mild hypothermia both during and after laparotomy has several adverse effects.[1 2] Various non-invasive methods have been tried to prevent and treat mild perioperative hypothermia. As most metabolic heat is lost through the skin surface, active cutaneous heating is the main principle of most devices. Circulating-water mattresses, forced-air warmers, resistive heating, and radiant warmers are all in clinical use.[2 3] Recently, systems using a combination of heat and mild constant negative pressure to increase the cutaneous blood circulation have been proposed. Recovery from mild hypothermia has been shown to be moderately accelerated by this method.[4–6] The mechanism is claimed to be that mechanical distension of peripheral vessels overrides thermoregulatory vasoconstriction,[7] thus improving the transfer of heat from the external source to the peripheral blood and thence to the core of the body. However, further studies showed no effect of negative pressure in this context.[8] A possible explanation of this is provided by the finding that continuous negative pressure reduces blood flow locally via the veno-arterial reflex, which causes arterial vasoconstriction in response to the distension of venous vessels.[9 10] We hypothesized that pulsating negative pressure would perform better by increasing blood flow and heat transfer. In this clinical study, we

†*Declaration of interest.* According to University Innovation policy, a patent was filed in connection with the development of the apparatus used in this study (UK). Later, patents were filed in several other countries, including Europe and USA. A limited liability company in Norway, Thermonor, is pursuing the commercial interests. E. B. Rein and M. Filtvedt have commercial interests in an eventual product.

have tested the hypothesis that negative pulsating pressure and warm water applied locally could effectively reverse perioperative hypothermia. A well documented, efficient forced air-warming system, that is, Bair Hugger®, was used as a comparator.

Materials and methods

The study was carried out at the main operating theatre at Ullevål University Hospital. The regional ethics committee approved the study, and written informed consent was obtained from all patients. All equipment used in this study met the criteria laid down by the Norwegian Directorate for Civil Protection and Emergency Planning and was also approved by the Department of Electro-Medical Equipment at Ullevål University Hospital.

Subjects

Patients who were to undergo laparotomy for major abdominal surgery were asked to participate in the study. Each operation was expected to last for at least 2 h. All patients were fasted from midnight the day before. Criteria for exclusion were skin lesions on the right arm, vascular diseases, diabetes, fever, arthritis, and rheumatic diseases. The patients were randomized into two groups by a computer program (Microsoft® Office Excel). One group of patients received treatment with locally applied warm water and pulsating negative pressure, called the new method (NM). The other group was treated using the Department's normal method, which was forced-air warming using warm air blankets. This was called the standard method (SM).

Experimental design

Patients treated with NM rested in the supine position on the operating table. The right arm was abducted 70–90° and positioned inside a custom-built tube-shaped transparent Plexiglass chamber, 50×16 cm (Figs 1 and 2). The chamber was sealed to the proximal part of the arm by a neoprene collar, which was attached to an adapter (10×16 cm). An elastic rubber sleeve ran from the proximal neoprene collar to the Plexiglass cylinder making the tube watertight. Warm water at 42.5°C was circulated between the cylinder and a thermostat-regulated water-bath. The water-bath was connected to the chamber by two insulated latex hoses. A peristaltic pump circulated the water at 3.5 litre min^{-1}. Two independent alarm systems were attached to prevent accidental overheating. The chamber was three-quarters full of water, leaving an air pocket from which the air could be evacuated to give negative pressure. The pressure inside the chamber was pulsated between 0 (=ambient pressure) and −40 mm Hg. The chamber was connected to an adjustable medical suction device. A pair of computer-controlled magnetic valves were connected between the chamber and the suction device. A computer program controlled the opening and closing of the valves. When a magnetic valve opened, air was evacuated by the suction and pressure fell inside the tube. After 10 s the valve was closed, another valve opened, and air from the surroundings could freely pass into the tube for the next 7 s as pressure rose back to atmospheric pressure. The pressure inside was measured continuously. The pressure waveform had a saw tooth shape. The cycle of 10 s on and 7 s off was based on empirical data from pilot studies.

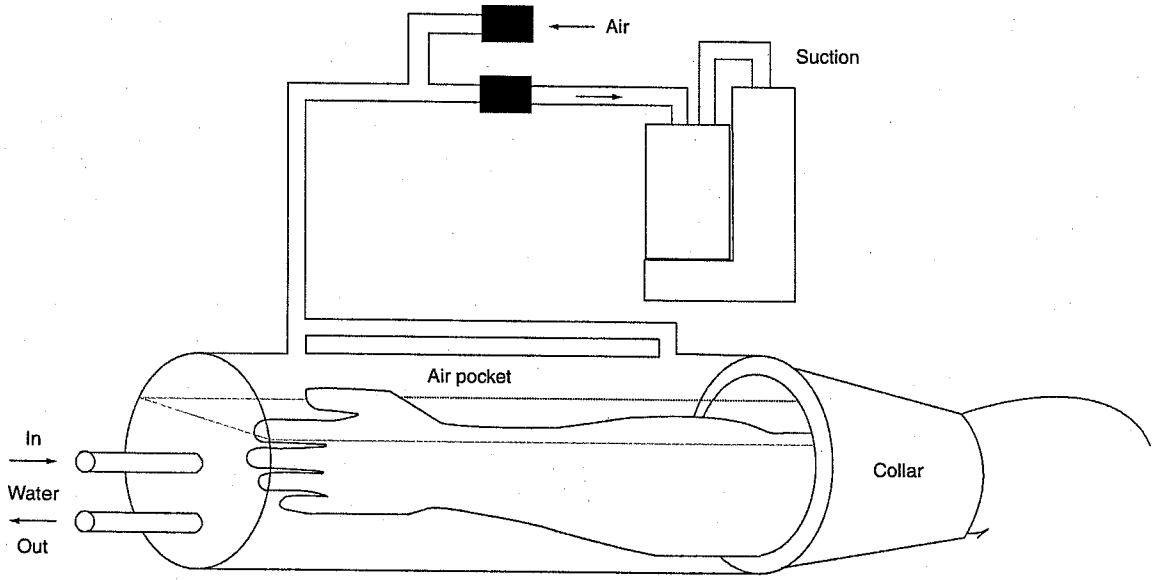

Fig 1 Cylindrical transparent Plexiglass chamber (50×16 cm), sealed to the upper arm by a neoprene collar attached to an adapter (10×16 cm). An elastic rubber sleeve ran from the proximal neoprene collar to the Plexiglass cylinder making the tube watertight.

Fig 2 Picture taken from head-end of operating table showing new method used on patient: Plexiglass cylinder on patient's right arm. Hoses for evacuation of air (top) and circulating water (end) attached to cylinder. The Anaesthesiologist is covering patient's face. (Photograph reproduced with the patient's permission.)

Table 1 Comparison of the two groups, NM and SM, n=10 in each group. Data are median (range) or mean (SD)

Variables	New method	Standard method
Subjects		
Age (yr)	70 (41–81)	63 (43–87)
Weight (kg)	70.20 (11.49)	66.67 (16.19)
Height (cm)	1.75 (0.09)	1.68 (0.08)
BMI (kg m^{-2})	23.0 (18.3–26.4)	21.0 (18.3–36.1)
Operation method		
Laparatomy	10	10
Additional thoracotomy		2
Operation variables		
Core temperature before anaesthesia (°C)	36.7 (36.4–37.0)	36.9 (35.8–37.0)
Total duration of surgery (h)	2.9 (1.4–6.8)	2.7 (1.3–4.83)
Total duration of anesthesia (h)	3.9 (2.2–6.8)	3.7 (2.3–6.0)
Time from anaesthesia to warming (min)	20 (10–45)	30 (20–75)
Room temperature (°C)	22 (21–24)	21.0 (20–22)
Room humidity (%)	39 (31–55)	42 (32–66)
Haemoglobin (g dl^{-1})	13.9 (10.3–15.8)	13.3 (10.3–15.2)
Fluids given i.v. (ml)*	5750 (3500–10 650)	5800 (4300–8300)
Diuresis (ml)	303 (0–1063)	244 (0–1175)
Blood loss (ml)	475 (150–2500)	500 (200–1140)
Peritoneal lavage (litre)	2 (1–2)	2 (0–3)

*Ringer acetate, Makrodex, Haemaccel, Voluven, NaCl, SAG, Haes.

The SM group received the hospital's standard treatment, forced-air warming, using Bair Hugger® warm air blankets. The blankets covered the thorax and abdomen above the incision, both arms, neck, and sometimes the legs if practical. The anaesthetic personnel operated this system and were instructed to prevent hypothermia according to hospital standards and to follow their normal routine. This is to use forced air at 43°C and maximal air flow until normothermia is re-established.

All i.v. fluid was pre-heated to 37°C in a heating chamber before infusion, as was fluid for peritoneal lavage. Blood was warmed during infusion with a blood warmer. Swabs were pre-heated in a liquid water-bath, holding 37°C. This is standard procedure and was identical in both groups. The operating room temperature and humidity was set centrally for entire theatre wing and measured locally and noted regularly during surgery (Table 1). Active warming with SM or NM was started as soon as possible after induction of anaesthesia.

Measurements

The core temperature was measured continuously using a tympanic probe[11] (Exacon, model 8940, Denmark) starting before induction of anaesthesia, and data were fed online to a computer and recorded at 2 Hz. To standardize the measurements as far as possible the probe was inserted by the same person every time. The probe was securely fastened to the ear and neck with adhesive plaster to avoid movement of the probe during patient handling. Cotton was inserted into the distal 1–2 cm of the external ear canal to isolate the probe and prevent air from the surroundings from interfering with the readings. Because measurements were made continuously and displayed real-time on a computer screen, any sudden non-physiological change in temperature, for example, if a probe was pulled away from the tympanic membrane was seen and corrected. In addition, oesophageal and rectal temperature probes were used when possible to confirm the readings of the tympanic probe.

Data analysis and statistics

Because the surgical equipment generated some electrical noise, the continuous data from the tympanic temperature were manually read and edited after the study. The temperature was noted at 10 min intervals for analysis. The primary endpoint was the tympanic temperature at 120 min. The changes in tympanic temperature between baseline (at induction of anaesthesia) and 120 min (ΔT after 120 min) were compared between the two groups. The differences in temperature change between the groups at 60 min after induction of anaesthesia (ΔT after 60 min) were also calculated. The Wilcoxon two-sample test was used to test for significant differences in ΔT between the two groups. Even though the patients were randomized to the two treatment groups, possible differences in patient characteristics and other confounding factors were tested by a *post hoc* stepwise multiple linear regression analysis. All anthropometric variables and all variables from Table 1, in addition to the warming method, were possible explanatory variables in the analyses and ΔT was the dependent variable. All the analyses were performed using the statistical program SPSS. Differences were considered significant at $P<0.05$.

Results

Three patients whom we approached refused to participate in this study. Twenty patients, 9 females and 11 males

agreed to take part. Patient characteristics, type of operation, and operation variables are listed in Table 1. There was a gender difference between the two groups. In the NM group, there were three female patients age [median (range)] 73 (70–81) yr and seven male patients age 73 (70–81) yr. In the SM group, there were six female patients age 57.5 (43–87) yr and four male patients age 77 (63–78) yr. Active warming started on average 10 min later in the SM group, and lasted for 175 (range 130–280) min in the NM group, as compared with 246 (range 130–350) min in the SM group. Warming was shorter in the NM group because the warming device had to be turned off to prevent over-heating of patient. Duration of anaesthesia and surgery was similar in the two groups (Table 1).

The new method resulted in significantly faster re-establishment and maintenance of body temperature than the standard method after 120 min. Stepwise multiple linear regression showed that the only significant variable in addition to the warming method was patient height. ΔT decreased by 2°C for each metre increase in height (P=0.036). When the results were adjusted for this variable, the difference in ΔT between the two methods increased from 0.92°C to 1.00°C.

Figure 3 shows averaged normalized values for both groups. The highest registered starting temperature in each group was 37.0°C, and the two groups were therefore normalized by addition, making all experiments start at 37.0°C. In the NM group, the mean temperature initially decreased by 0.7°C in the course of 50 min, before increasing and returning to the starting value after 130 min. In the SM group, the temperature decreased 1°C beyond 80 min and then remained stable at this level throughout the operation.

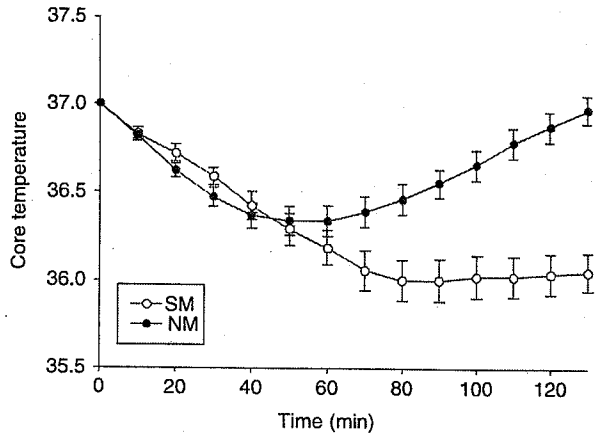

Fig 3 Averaged normalized tympanic temperatures from both groups. The graphs are normalized by adding, making all experiments start at 37.0°C. Induction of anaesthesia is at 0 min. Error bars are plus and minus one standard error.

Discussion

The main finding in this study is that locally applied warm water and pulsating negative pressure is significantly better than the Bair Hugger® forced-air warming system in preventing and treating mild perioperative hypothermia during abdominal surgery. Abdominal surgery is known to cause mild hypothermia, probably because of the prolonged duration of surgery, the large incision required and the frequent use of peritoneal lavage.[12] Most of our patients were operated on as part of cancer treatment. These patients are often elderly, a patient group which is known to be prone to hypothermia.[13] In our study, the median ages were 70 yr in NM group and 63 yr in SM group. We would have expected our patients to suffer from mild hypothermia if no treatment had been given.

Without treatment, intraoperative hypothermia develops in three phases.[1 14] In phase 1, hypothermia results from a core-to-peripheral redistribution of heat after induction of general anaesthesia (GA) and subsequent immediate vasodilatation. General anaesthesia also reduces the threshold for cutaneous heat-loss protective vasoconstriction to a level below current body temperature leading to dilation of arterioles and AV-anastomoses. This produces a decrease in body core temperature of approximately 1.5°C within the first hour if unopposed. In phase 2, the core temperature decreases linearly, but at a slower rate, because body heat loss exceeds heat gain. In phase 3, after 3–5 h of anaesthesia, heat loss equals heat gain. A stable plateau with core temperatures about 2–3°C below baseline is usually reached, depending on the temperature in the environment and how well the patient is protected from heat loss. In our study, both groups showed an initial decrease in core temperature (ΔT). None of the patients were pre-heated, and therefore, the temperature decrease was expected. The temperature decrease in the SM group was 0.3°C larger and a nadir was reached 30 min later at 1.0°C below baseline levels. There may be several different explanations for this. Warming was started 10 min later in the SM group, allowing the temperature to decrease further than in the NM group before warming could take effect. The reason for this delay was washing and draping of the surgical field before the airflow blankets could be applied. Airflow blankets ideally need to cover as close to the surgically washed and draped field of the abdomen as possible in order to utilize a maximum area of skin exposure for best effect. This conflict with sterile draping and delay in application is not present for the NM group during laparotomy when an arm is used for heat application. This practical aspect was also illustrated by coincidence in our study as two of the patients (in the NM group) needed extension of the surgical field into thorax. However, both methods were equally easy to start and operate. In both groups, the average temperature decreased at about 0.8°C h^{-1}, thus a 10 min delay would equal a decrease in temperature of just under 0.2°C.

Another explanation of difference in temperature decrease could be the modest difference in BMI. Preoperatively, a patient with a high BMI tends to be more vasodilated than a patient with a low BMI. This is due to the insulating effects of fat tissue, which makes the dissipation of heat in adipose people dependent on high skin blood flow. This decreases the core-to-peripheral temperature gradient and results in a smaller decrease in temperature during phase 1 of perioperative hypothermia. However, the stepwise multiple linear regression analyses did not identify BMI as a significant variable for the differences in core temperature after 120 min. There was also a gender difference between the two groups, with more females, and a wider age range (43–87 yr), in the NM group. Several studies on human temperature regulation have shown gender differences.[15] These studies are mainly on eumenorrheic women. Not many studies have been performed on gender differences in the older population during perioperative hypothermia. A study on subjects that were awake showed that all thermoregulatory response thresholds, that is, sweating, vasoconstriction, and shivering, were 0.3°C wider in women.[16] A study on thermoregulatory vasoconstriction during nitrous oxide/isoflurane anaesthesia showed a lower threshold for elderly patients, but no gender difference.[17] Our regression analysis did not reveal an effect of age or gender. However, the small sample size means that this analysis had limited power. The last, and most obvious, explanation for the difference in temperature decrease between the two groups is a difference in efficacy between the two warming methods. The NM brought the core temperature in all patients back to baseline levels. In the SM group, the average core temperature reached a plateau at 1.0°C below baseline level. This is still better than expected without any treatment, confirming that forced-air warming does have an effect.

Forced-air warming has been extensively tested,[1 3 14 18–26] and is now the preferred warming system in many hospitals.[3] During laparotomy, a large section of the abdominal skin surface is unavailable for forced-air heating, in addition to the part of the patient that is in contact with the operating table. The efficacy of the forced-air warming system is dependent on a large skin surface for heat transfer. In addition, heat uptake is dependent on skin blood flow in the heated area. Another limiting factor is the thermal conductivity of air, which is low, 0.025 ($W\ m^{-1}\ °C^{-1}$).

There may be several explanations for the efficacy of the NM. The use of water increases heat transfer because the thermal conductivity of water (0.600 $W\ m^{-1}\ °C^{-1}$) is 25 times higher than that of air. Water also connects better with the skin, entering every fold and groove. Finally, and perhaps most important, the pulsating negative pressure probably increases blood flow. A pilot study done in our laboratories, using the ultrasound Doppler method, showed that local blood flow could be increased by at least 43% by pulsating the negative pressure in the same manner as done in our study. The increase in blood flow can be explained by an increase in the pressure difference between the arterial and venous system and by avoidance of the veno-arterial reflex, which constricts the arterioles when the veins are distended.[3 10] An additional feature may be pooling of blood in the veins, bringing more blood closer to the surface for heat exchange.

In conclusion, the new method using warm water and pulsating negative pressure was significantly better in preventing and reversing hypothermia during laparotomy than forced-air warming (Bair Hugger®).

Acknowledgements

First, we would like to thank our surgical colleagues for their excellent cooperation. We would also like to thank Dr Morten Eriksen who helped us with programming, the technicians at the Institute of Basic Medical Sciences two workshops for excellent help, the Department of Electro-Medical Equipment at Ullevål University Hospital for technical assistance and testing, and the Norwegian Army, Medical Branch, for scholarship funding.

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RELATED PROCEEDINGS APPENDIX

None.